

SETINO®



Vinyl / Nitrile Blended GLOVES



**EN
455**



FDA



INDEX

Group introduction.....	3
Product description and pictures.....	4
Disposable nitrile/vinyl gloves box/carton.....	6
Certificates	
Medical Device Quality Management System EN ISO 13485	
Certificate ISO 9001 Quality Management System Certificate.....	10
EC DoC MDR 2017/745 EU.....	29
EC DoC PPE 2016/425 EU.....	31
EU Medical Device Regulation Coordination Standard (EN455)	
Certificate and product test report.....	32
EN ISO 374 EU Type Examination Certificate.....	33
Protocol for shelf-life determination study	35
Performance testing report at time zero.....	37
Summary for accelerated aging shelf-life testing.....	41
EN 455-1:2000, EN 455-2:2015, En 455-3:2015 test report.....	43
Specification for VitriLe Examination Gloves.....	55
Certificate for exportation of medical products.....	56
Food contact test report.....	61
EC REP registration.....	85

INDEX

FDA Annual Registration Information.....	86
Dermal irritation test report.....	87
EN ISO 374-5 - resistance to penetration by blood-borne pathogens, test report.....	109
EN 16523-1 - resistance to permeation by chemicals, test report.....	114
EN ISO 374-5 - resistance to degradation by dangerous chemicals, test report.....	122
EN ISO 21420 - size, dexterity and innocuousness, EN 374-2 air and water leak test report.....	127
BSCI Audit Report - Everlight.....	136
BSCI Audit Report - Better care.....	151

GROUP INTRODUCTION

Dedicated to the glove industry for more than 20 years

- Shijiazhuang Hongray Group is one of the leading manufacturer of disposable protective gloves in the world
- Our group has five major production bases in Shijiazhuang, Jinzhou, Xinji, Zhanhuang, Shenze of Hebei Province
- We produce various vinyl gloves nitrile gloves, PE and non-woven series products with the annual output of 14 billion pieces of gloves
- Product are widely used in field of medical examination, first-aid, nurse, dentistry, laboratories, food processing and electronic industry protection etc.
- Strict quality assurance system, rich professional experiences and well-trained staff, high quality product and services
- Our products sell well in many regions and countries worldwide:



PRODUCT DESCRIPTION AND PICTURES


The Vinyl/Nitrile Blend (Vitrile) gloves is compounded with PVC paste and Nitrile latex, and the finished product has the advantage of both PVC and Nitrile glove.

- Product name: Powder free Vitrile Examination Gloves
 - Single use, non-sterile, no measuring, latex free
 - Sizes: S, M, L, XL, XXL
 - Colors: Blue, Purple Blue
 - Structure: 5 fingers, beaded cuff for easy donning, ambidextrous
 - Surface: Textured on fingers
- Donning feeling better than vinyl gloves
 - Softer than vinyl gloves
 - Easy donning with wet hands and easier donning than nitrile & vinyl gloves.
 - The shelf life is longer than nitrile gloves.

Intended purpose: The examination gloves are disposable non-sterile devices intended for medical purpose that are worn on the examiner's hand and fingers to prevent contamination between patient and examiner.

• Pictures:



Size	Length (mm)	Width (mm)(mm)	Single glove weight (+/-0.2)	Carton gross weight	Barcode
S	240	80+/-10	5.5 g	6.5 kg	 5 991326 502345
M	240	95+/-10	6.0 g	7.0 kg	 5 991326 502352
L	240	105+/-10	6.5 g	7.5 kg	 5 991326 502369
XL	240	115+/-10	7.0 g	8.0 kg	 5 991326 502376

Two boxes of SETINO Disposable Vinyl/Nitrile Examination Blend Gloves are shown. The top box is blue and white, displaying the front and side. The bottom box is white and blue, displaying the back. Dimensions are indicated: 240 mm (length), 120 mm (width), and 70 mm (height). A 'MEDICAL' label is present in the bottom right.



DISPOSABLE VINYL/NITRILE GLOVES CARTON - MD



365 x 250 x 255 mm

MEDICAL

Box size (M): 240 x 120 x 70 mm
Carton size (M): 365 x 250 x 255 cm

S	M	L	XL
10%	40%	40%	10%

Box	Carton	Pallet	20GP	40GP	40HQ
100pcs	10 boxes	84 cartons	1200 cartons	2500 cartons	2950 cartons/ 29500 boxes

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DISPOSABLE VINYL/NITRILE GLOVES CARTON - PPE



365 x 250 x 255 mm

PPE

Box size (M): 240 x 120 x 70 mm
Carton size (M): 365 x 250 x 255 cm

S	M	L	XL
10%	40%	40%	10%

Box	Carton	Pallet	20GP	40GP	40HQ
100pcs	10 boxes	84 cartons	1200 cartons	2500 cartons	2950 cartons/ 29500 boxes

--	--	--	--

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shijiazhuang Hongray
Group Co., Ltd.**
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Patient Examination Gloves
(see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-09-30
Certificate Registration No.: SX 60151704 0001
An audit was performed. Report No.: 16801058 009
This Certificate is valid until: 2023-04-25

Certification Body



Date 2020-09-30



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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Date 2020-09-30



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc 2/3, Rev 0

**Attachment to
Certificate**

Registration No.: SX 60151704 0001
Report No.: 16801058 009

Organization: Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Shijiazhuang Jiahe Plastic Glove Co., Ltd.
Western Jiafeng Road, Mining Area, Shijiazhuang,
050100, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.
Donggao Industrial Zone, Zhanhuang, Shijiazhuang,
050000, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base,
Shenze County, 050000, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Certification Body



Date: 2020-09-30



Wenxiang Zhang

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc 3/3, Rev 0

**Attachment to
Certificate**

Registration No.: SX 60151704 0001
Report No.: 16801058 009

Organization: Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Hong Di Plastic Products Co., Ltd.
Donggao Industrial Zone, Zhanhuang, 050000, Hebei, P.R. China

Manufacture of Patient Examination Gloves

Shanxi Hongjin Plastic Technology Co., LTD.
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, 042300, Shanxi, P.R. China

Manufacture of Patient Examination Gloves

Certification Body



Date: 2020-09-30



Wenxiang Zhang

Business Stream Products
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 HEBEI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 16, 2020

Application for : QMS

Certificate No. : SX 60148697 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60148697 0001
replacing the previous certificate.

Kind regards

Certification body

A handwritten signature in blue ink, appearing to read 'Jing Zhang'.

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

No.	Location	Scope
/01	Shijiazhuang Hongray Group Co., Ltd. Unified Social Credit Code: 91130100728799919R Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above	Distribution of Patient Examination Gloves
/02	Syntex Healthcare Products Co., Ltd. Unified Social Credit Code: 91130181734364356G Registration Address: Southern No. 307 National Highway Rd., Western Fanjiazhuang Village, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/03	Grand Work Plastic Products Co., Ltd. Unified Social Credit Code: 91130100752433415G Registration Address: Donggao Industrial Zone, Zhanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

- | | | |
|-----|--|--|
| /06 | <p>Shijiazhuang Jiahe Plastic Glove Co., Ltd.
Unified Social Credit Code: 91130107563240147C
Registration Address:
Northern Jiandi Village,
Western Jiafeng Road,
Mining Area, Shijiazhuang City,
050100 Hebei, P. R. China
Operation Address: same as above</p> | Manufacture and Distribution of Patient Examination Gloves |
| /08 | <p>Purtech Cleanroom Products Co., Ltd.
Unified Social Credit Code: 91130181777701957N
Registration Address:
Fanjiashuang Industrial Zone,
Xinji City, 052360 Hebei,
P. R. China
Operation Address: same as above</p> | Manufacture and Distribution of Patient Examination Gloves |
| /09 | <p>Ever Light Plastic Products Co., Ltd.
Unified Social Credit Code: 91130100784064765D
Registration Address:
Donggao Industrial Zone,
Zanhuang, 050000 Hebei,
P. R. China
Operation Address: same as above</p> | Manufacture and Distribution of Patient Examination Gloves |

Annex to certificate

Standard

ISO 9001:2015

Certificate Registr. No. **01 100 1732303**

- | | | |
|-----|--|---|
| /10 | <p>Better Care Plastic Technology Co., Ltd.
Unified Social Credit Code:
911301286920575093
Registration Address:
Shenze Industrial Base (Fuqian Xi Road), Shenze County,
050000 Hebei, P. R. China
Operation Address: same as above</p> | <p>Manufacture and Distribution of Patient Examination Gloves</p> |
| /11 | <p>Shijiazhuang Hongzan Plastic Technology Co., Ltd.
Unified Social Credit Code:
91130129567387090Y
Registration Address:
Donggao Industrial Zone,
Zanhuang, Shijiazhuang City,
050000 Hebei, P. R. China
Operation Address: same as above</p> | <p>Manufacture and Distribution of Patient Examination Gloves</p> |

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/12

Shanxi Hongjin Plastic
Technology Co., Ltd.
Unified Social Credit Code:
91141030MA0HDY6R5D
Registration Address:
Coal Bed Gas Industrial Zone,
Qu'e Town, Daning County,
Linfen City, 042300 Shanxi,
P. R. China
Operation Address: same as
above

Manufacture and Distribution of Patient
Examination Gloves

2020-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 4 of 4

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/01**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Shijiazhuang Hongray Group Co., Ltd.**
Unified Social Credit Code: 91130100728799919R
Registration Address: South Tongda Rd., East Dist.,
Jinzhou City, 052260 Hebei, P. R. China
Operation Address: same as above

Scope: Distribution of Patient Examination Gloves

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/02**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Syntex Healthcare Products Co., Ltd.**
Unified Social Credit Code: 91130181734364356G
Registration Address: Southern No. 307 National Highway Rd.,
Western Fanjiazhuang Village, Xinji City,
052360 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01
100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2020-08-18



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/03**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Grand Work Plastic Products Co., Ltd.**
Unified Social Credit Code: 91130100752433415G
Registration Address: Donggao Industrial Zone,
Zanhuang, 050000 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-08-18



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/06**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Shijiazhuang Jiahe Plastic Glove Co., Ltd.**
Unified Social Credit Code: 91130107563240147C
Registration Address: Northern Jiandi Village,
Western Jiafeng Road, Mining Area, Shijiazhuang City,
050100 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-08-18



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/08**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Purtech Cleanroom Products Co., Ltd.**
Unified Social Credit Code: 91130181777701957N
Registration Address: Fanjiazhuang Industrial Zone,
Xinji City, 052360 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-08-18



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/09**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Ever Light Plastic Products Co., Ltd.**
Unified Social Credit Code: 91130100784064765D
Registration Address: Donggao Industrial Zone, Zanhuang,
050000 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01
100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2020-08-18



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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/10**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Better Care Plastic Technology Co., Ltd.**
Unified Social Credit Code: 911301286920575093
Registration Address: Shenze Industrial Base (Fuqian Xi Road),
Shenze County, 050000 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01
100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2020-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/11**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Shijiazhuang Hongzan Plastic Technology Co., Ltd.**
Unified Social Credit Code: 91130129567387090Y
Registration Address: Donggao Industrial Zone, Zanhuang,
Shijiazhuang City, 050000 Hebei, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01
100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2020-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303/12**

Organization: **Shijiazhuang Hongray Group Co., Ltd.**
South Tongda Rd., East Dist., Jinzhou City,
052260 Hebei, P. R. China

Site: **c/o Shanxi Hongjin Plastic Technology Co., Ltd.**
Unified Social Credit Code: 91141030MA0HDY6R5D
Registration Address: Coal Bed Gas Industrial Zone,
Qu'e Town, Daning County, Linfen City,
042300 Shanxi, P. R. China
Operation Address: same as above

Scope: **Manufacture and Distribution of Patient Examination Gloves**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid in conjunction with the main certificate 01 100 1732303 from 2020-10-20 until 2023-04-19.
It remains valid subject to satisfactory surveillance audits.

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-08-18



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EC Declaration of Conformity

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260
Hebei, China.
Tel: +86-311-83610904
Fax: +86-311-83610904

Distributor:

Setino Hungary Kft.
Száva 4/B 1107
Budapest, Hungary
Tel.: +36-1-349-1053

We, the manufacturer, herewith declare that the products

Disposable Vinyl / Nitrile Examination Glove

UMDNS-Code: 11-882

Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU.



This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.


Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China.

Jinzhou China 2020-04-01

Place, date

GM:  *Manager*
Legally binding signature, Function

EC Declaration of Conformity

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260
Hebei, China.
Tel: +86-311-83610904
Fax: +86-311-83610904

whose single Authorized Representative:

Caretechion GmbH
Niederrheinstr. 71, 40474 Düsseldorf,
Germany
DIMDI Code: DE/0000048026
Tel/Fax: 0211 3003 6618
Email: info@caretechion.de

We, the manufacturer, herewith declare that the products

Disposable Vinyl/Nitrile Blend Examination Gloves

With the size of XS, S, M, L, XL and XXL

UMDNS-Code: 11-882

UDI:

Meet the provisions of MDR 2017/745 EU which apply to them.

The medical device has been assigned to class I according to Annex VIII of the MDR 2017/745 EU.



Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

The glove is a disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

The product concerned has been manufactured under a quality management system according to Annex IX of MDR 2017/745 EU.

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of MDR 2017/745 EU.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China.

Jinzhou China 2020-05-10

Place, date

EC Declaration of Conformity

GM:

Legally binding signature, Function



CE TECHNICAL DOCUMENTATION REVIEW REPORT

Company Name: Shijiazhuang Hongray Group Co. Ltd.

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260, China

Review Intention: Review the completeness of the Technical Documentation according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III

Product(s): Disposable Vinyl/Nitrile Blend Examination Gloves

Type(s) / Model(s): Powder Free / XS, S, M, L, XL, XXL

Classification: Class I
(According to Annex IX Section III 1.1 and 1.4 of the Medical Devices Directive 93/42/EEC & Annex VIII Chapter III 4.1 rule 1 of Medical Device Regulations 2017/745)

Review period: January 20, 2020

Review Result: During the examination of the Technical Documentation (No: HRG-JSWJ-003, Revision: A, Dated 2020-01-15), no non-compliance according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III was detected.

Signature: Wu Min

Date: January 20, 2020

Regulatory Authority

EU DECLARATION OF CONFORMITY

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260
Hebei, China
Tel.: +86-311-83610904
Fax: +86-311-83610904

Distributor:

Setino Hungary Kft.
Száva 4/B 1107
Budapest, Hungary
Tel.: +36-1-349-1053

under its sole responsibility declares, that the personal protective equipment specified below:

**Disposable Vinyl / Nitrile Blend Glove
VNPF2001-2005
SETINO CODE: VN-3**

was classified in category III. - PPE (EU) 2016/425 II. according to its annex
EN ISO 374-1: 2016; EN ISO374-4:2019; EN ISO 374-5: 2016; EN ISO21 420:2020

EN ISO 374-5:2016



VIRUS

EN ISO 374-1:2016



K - Low Chemical

The protective equipment complies with the requirements of Regulation 2016/425 (EU) and the harmonized European standards EN ISO 374-1: 2016, EN ISO 374-5: 2016, EN ISO374-4:2019, EN ISO21 420:2020 and identical to PPE covered by EU type examination (Module B); certificate number: 2777/15012-01/E00-00.

Issuing certification body:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland
Notified Body: 2777**

According to module C2 for PPE, a conformity assessment procedure is carried out under the supervision of the notified body, supervising:

**SATRA Technology Europe Limited. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland
Notified Body: 2777**

**Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist. Jinzhou, 052260 Hebei, China**

2020.10.16.

Place, date



[Signature]

Signature

EU Type-Examination Certificate

Certificate number: 2777/15012-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:

Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

VNPF2001-2005

Description:

Disposable Vinyl/Nitrile Blend Examination Gloves.

Colour: Blue, Green, Black.

Sizes:

XS(6)-XL(10)

Classification:

EN ISO 374-1:2016+A1:2018/ Type B	Level	EN ISO 374-4:2019 Degradation %
40% Sodium hydroxide (K)	6	-1.2
30% Hydrogen peroxide (P)	6	2.7
37% Formaldehyde (T)	6	-8.1

EN ISO 374-5:2016

Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

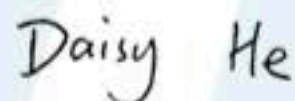
Standards/Technical specifications applied:

EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:

SATRA: CHT0298236/2021, CHM0298451/2022/LH/A, CHM0298451/2022/LH/B, CHM0298451/2022/EN/C

Signed on behalf of SATRA:



Daisy He



Quincey Brown

Date first issued: 08/09/2020

Date of issue: 08/09/2020

Expiry date: 08/09/2025

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity.

Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

SHIJIAZHUANG HONGRAY GROUP CO., LTD.

PROTOCOL FOR SHELF LIFE DETERMINATION STUDY

1.0 Purpose:

Conduct shelf life determination for Disposable Vinyl/Nitrile Blend Examination Gloves as per EN455-4, so as to determine its shelf life.

2.0 Standard:

2.1 EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

3.0 Samples Information:

Size: M

Product Name: Disposable Vinyl/Nitrile Blend Examination Gloves

Product Lot No. and quantity: Random sample three production lots from production lines of Grand Work Plastic Products Co., Ltd. (10 cases per lot, and 1000 pieces/ case), conduct shelf life determination study per item 5.1-5.3.

4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero, accelerated aging or real time shelf life determination.

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		$95 \pm 10\text{mm}$	13 pieces, median
Thickness (mm)	Middle Fingertip t_f	$t_f/t_x \geq 0.9$	13 pieces
	Test piece t_x		
Force at Break (N)		$\geq 3.6\text{N}$	13 pieces, median
Watertightness		---	G-I, AQL1.5, sampling 80 pieces (Ac3, Re 4)

Notes:

1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$, Humidity: $50 \pm 5\%$
2. Samples shall be conditioned at least 16 hours before testing.

If all the testing results comply with the criteria requirements then the lot of products will be accepted. On the contrary, it will be rejected.

5.0 Shelf Life Determination Study:

5.1 Time Zero Testing:

5.1.1 It is estimated to conduct time zero testing for Vinyl gloves from January 20, 2020. The

testing will be conducted and recorded per item 4.0 after the randomly sampled gloves are conditioned. Analyze the testing data so as to ensure that original testing data for the gloves for shelf life determination comply with standard requirements.

5.1.2 If it is determined that the time zero testing result comply with standard requirements, start accelerated aging shelf life determination study and real time study.

5.2 Accelerated Aging Shelf Life Testing:

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5 time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 170 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	110 Days

5.2.2 As per the arrangements in the above table, the schedules for each testing are as follows:

Temp	80°C	70°C	60°C	50°C
Testing Period	Estimated testing period is: 2020.01.20-01.25	Estimated testing period is: 2020.01.26-02.05	Estimated testing period is: 2020.02.06-03.19	Estimated testing period is: 2020.01.20-05.10

5.2.3 Conduct accelerated aging for 3 lots of products at each selected temperature and time, and make relative testing and records as per item 4.0 after completing accelerated aging. Analyze and evaluate each testing data after each testing.

6.0 Standard for Shelf Life Determination

6.1 Shelf life determination for accelerated aging shelf life testing: After completing relative testing required in item 5.1 and 5.2, if each testing data comply with EN 455-1 and EN 455-2, then it is acceptable to claim that the shelf life of the gloves is 3 years.

6.2 It is not acceptable to claim that the shelf life of the Vinyl Gloves is 5 years till the real time testing is completed.

7.0 Record and Files:

Details for shelf life determination study refer to corresponding testing report, and the testing data and report shall be filed permanently.

Prepared by:  / QA Director of Grand Work

Date: January 18, 2020

Reviewed by:  / QA Director of Hongray Group

Date: January 18, 2020

SHIJIAZHUANG HONGRAY GROUP CO., LTD.

PERFORMANCE TESTING REPORT AT TIME ZERO

Purpose:

As per EN455-4, carry out performance test at time zero to verify and determine whether the product of Disposable Vinyl/Nitrile Blend Examination Gloves conform to associate standard requirements, and provide basic data for determining shelf life of the product.

Date Tested: 2020.01.20

Samples Tested:

Gloves manufactured in current production lines of Grand Work Plastic Products Co., Ltd.

Machine No.: 4 Size: M

Product Name: Disposable Vinyl/Nitrile Blend Examination Gloves

Product Lot No.: 20012011042C

20012013042C

20012019042A

Standards:

EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

The detailed testing results of the samples above-mentioned are as follows:

I. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 20012011042C :

1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded result for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Geng Yali

Test Condition: 22°C, 51%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	242	0.08	0.08	96	3.8
2	M	235	0.08	0.08	97	3.9
3	M	240	0.08	0.08	96	4.1
4	M	238	0.08	0.08	97	4.0
5	M	241	0.08	0.08	97	3.6
6	M	233	0.08	0.08	96	4.0
7	M	241	0.08	0.08	97	3.9
8	M	241	0.08	0.08	97	4.2
9	M	240	0.08	0.08	97	4.0

10	M	242	0.08	0.08	97	4.0
11	M	235	0.08	0.08	97	4.0
12	M	240	0.08	0.08	97	3.6
13	M	242	0.08	0.08	97	3.9
Median Value						4.0

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break $\geq 3.6\text{N}$).

2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Geng Yali, Wang Qiaoran

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

3. FINAL RESULTS of LOT NO. 20012011042C :

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

II. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 20012013042C

1. PERFORMANCE TESTING AT TIME ZERO----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Geng Yali

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	237	0.08	0.08	96	4.2
2	M	240	0.08	0.08	97	4.0
3	M	242	0.08	0.08	97	3.8
4	M	240	0.08	0.08	97	4.2
5	M	240	0.08	0.08	96	3.9
6	M	242	0.08	0.08	96	4.0
7	M	242	0.08	0.08	97	3.8
8	M	242	0.08	0.08	97	4.2
9	M	233	0.08	0.08	96	3.9
10	M	239	0.08	0.08	97	4.0
11	M	234	0.08	0.08	97	3.7
12	M	245	0.08	0.08	96	3.6
13	M	238	0.08	0.08	96	3.9
Median Value						3.9

It is showed from the above data that the performance testing of samples conform to the It is It is

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break $\geq 3.6\text{N}$).

2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Geng Yali, Wang Qiaoran

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	2

It is showed from the above data that pinholes conform to requirements.

3. FINAL RESULTS of LOT NO. 20012013042C:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

III. PERFORMANCE TESTING RESULT AT TIME ZERO OF LOT NO. 20012019042A

1. PERFORMANCE TESTING AT TIME ZERO ----Dimensions and Physical Properties

Test Method: EN 455-4 & EN 455-2

Sample Size and Specification: 13 pieces of gloves were sampled, and the median of the recorded results for force at break shall conform to the values of at least 3.6N.

Conditioning: At least 16 hours

Tested by: Geng Yali

Test Condition: 21°C, 52%

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)
			Test Piece	Middle Fingertip		
1	M	241	0.08	0.08	97	3.9
2	M	245	0.08	0.08	97	3.6
3	M	243	0.08	0.08	96	3.8
4	M	236	0.08	0.08	96	3.6
5	M	240	0.08	0.08	96	4.0
6	M	245	0.08	0.08	97	3.8
7	M	236	0.08	0.08	97	4.2
8	M	232	0.08	0.08	97	3.6
9	M	241	0.08	0.08	96	4.0
10	M	242	0.08	0.08	97	4.2
11	M	248	0.08	0.08	96	3.7
12	M	243	0.08	0.08	97	4.0
13	M	235	0.08	0.08	97	3.9
Median Value						3.9

It is showed from the above data that the performance testing of samples conform to the specification (Force at Break $\geq 3.6\text{N}$).

2. Samples Pinhole Testing

Testing Standard and Method: EN455-4 & EN 455-1

Sample Size: per ISO2859, inspection level G-1, AQL=1.5

Tested by: Geng Yali, Wang Qiaoran

80pcs (Ac=3, Re=4)

Item	Size	Sample Count (pcs)	Pinhole (pcs)
Free from holes	M	80	1

It is showed from the above data that pinholes conform to requirements.

3. FINAL RESULTS of LOT NO. 20012019042A:

Final performance-testing results of samples conform to associate standard requirements, and can be used normally.

IV. FINAL RESULT FOR PERFORMANCE TESTING AT TIME ZERO:

Through the performance test at time zero on 3 lots products (Lot No: 20012011042C, 20012013042C, 20012019042A) as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and can be used normally.

Prepared by:  / QA Director of Grand Work

Date: January 20, 2020

Reviewed by:  / QA Director of Hongray Group

Date: January 20, 2020

SHIJIAZHUANG HONGRAY GROUP CO., LTD.

Summary for Accelerated Aging Shelf Life Testing

1.0 Purpose:

Conduct accelerated aging shelf life determination for Disposable Vinyl/Nitrile Blend Examination Gloves as per EN455-4, so as to determine its shelf life.

2.0 Standard:

2.1 EN 455-4: Medical Gloves for Single Use- Part 4 Requirements and Testing for Shelf life determination

2.2 EN 455-1: Medical Gloves for Single Use- Part 1 Requirements and testing for freedom from holes

2.3 EN 455-2: Medical Gloves for Single Use- Part 2 Requirements and testing for physical properties

3.0 Samples Information:

Gloves manufactured in current production lines of Grand Work Plastic Products Co., Ltd.

Machine No.: 4

Size: M

Product Name: Disposable Vinyl/Nitrile Blend Examination Gloves

Product Lot No.: 20012011042C

20012013042C

20012019042A

4.0 Instruction of Sampling Testing:

According to EN455-1 and EN455-2, sample gloves individually from three production lots and conduct the following testing and record the testing data under the condition of time zero and accelerated aging for shelf life determination.

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		$95 \pm 10\text{mm}$	13 pieces, median
Thickness (mm)	Middle Fingertip t_f	$t_f/t_x \geq 0.9$	13 pieces
	Test piece t_x		
Force at Break (N)		$\geq 6\text{N}$	13 pieces, median
Watertightness		---	G-I, AQL1.5, sampling 80 pieces (Ac3, Re 4)

Notes:

1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$, Humidity: $50 \pm 5\%$
2. Samples shall be conditioned at least 16 hours before testing.

If all the testing results comply with the criteria requirements then the lot of products will be accepted. On the contrary, it will be rejected.

5.0 Summary for Accelerated Aging Shelf Life Determination Study:

5.1 Time Zero Testing:

5.1.1 Time zero testing for Vinyl gloves were conducted from January 20, 2020. Based on the performance test results, it is showed that the samples meet associate standard requirements, and can be used normally and accelerated aging shelf life determination study and real time study were started subsequently.

5.2 Accelerated Aging Shelf Life Testing:

5.2.1 As per Annex B in EN 455-4, 4 different temperatures and 5 time point at each temperature are used for accelerated aging shelf life testing, and the testing is continued at least 180 days. The selected temperature and days are as follows:

# \ Temp	80°C	70°C	60°C	50°C
1	1 Day	1 Day	5 Days	22 Days
2	2 Days	3 Days	15 Days	35 Days
3	3 Days	7 Days	22 Days	55 Days
4	4 Days	8 Days	35 Days	90 Days
5	5 Days	10 Days	42 Days	110 Days

5.2.2 As per the arrangements in the above table, the actual schedules for each testing are as follows:

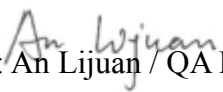
Temp \ Testing Period	80°C	70°C	60°C	50°C
	2020.01.20-25	2020.01.26-02.05	2020.02.06-03.19	2020.01.20-05.10

5.2.3 The accelerated aging testing was performed as per the above condition and schedule, and based on the accelerated aging performance testing results; it is showed that the samples meet associated standard requirements.

Details for accelerated aging testing for each condition refer to corresponding testing report.

5.3 Conclusion for accelerated aging performance testing:

Through the time zero and accelerated aging performance test according to the condition listed in section 5.1 and 5.2 on 3 lots products (namely Lot No: 20012011042C, 20012013042C, 20012019042A as per EN455-1, EN455-2, and EN 455-4, the final performance-testing results of samples conform to associate standard requirements, and the maximum shelf life of Disposable Vinyl/Nitrile Blend Examination Gloves determined by accelerated aging testing is 3 years.

Prepared by:  / QA Director of Grand Work

Date: May 10, 2020

Reviewed by:  / QA Director of Hongray Group

Date: May 10, 2020

Test Report No. 7191237837-EEC20/01-WBH
Dated 10 Jun 2020



PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by Shijiazhuang Hongray Group Co., Ltd
on 21 May 2020.

TESTED FOR:

Shijiazhuang Hongray Group Co., Ltd
South Tongda Rd., East Dist.,
Jinzhou City, Hebei,
052260, China

TEST DATE:

21 May 2020 to 10 Jun 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Lot No.	Colour	Size	Sample Received (pieces)
1	Disposable Vinyl/Nitrile Blend Examination Gloves	- (See Remark 1)	Blue	XS	61
				S	55
				M	329
				L	55
				XL	54
				XXL	60

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

The tests were conducted in accordance with the following standards as requested by client:

1. EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 4 Dimensions
-Clause 5 Strength
3. EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation
-Clause 4.4/5.2 Powder-free gloves



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1 Science Park Drive, #02-01
Singapore 118221
TÜV®

Test Report No. 7191237837-EEC20/01-WBH
Dated 10 Jun 2020



RESULTS:

Sample: Disposable Vinyl/Nitrile Blend Examination Gloves

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers Allowed (pieces)	Number Tested (pieces)	Actual No. of non-compliers Found (pieces)	Inferred Results
4 5	Freedom from holes	M	Shall not leak	7	200	0	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number Tested (pieces)	Results (Median)	Inferred Results
4	Dimensions a) Length (mm)	XS	≥ 240	13	245	Passed
		S	≥ 240	13	245	Passed
		M	≥ 240	13	248	Passed
		L	≥ 240	13	247	Passed
		XL	≥ 240	13	248	Passed
		XXL	≥ 240	13	259	Passed
	b) Width (mm)	XS	≤ 80	13	77	Passed
		S	80 ± 10	13	86	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	114	Passed
		XXL	≥ 110	13	123	Passed
5	Strength a) Force at break (N)	M	For vinyl examination gloves: ≥ 3.6	13	4.4	Passed
	b) Force at break after challenge testing (N) 7 days at $(70 \pm 2)^{\circ}\text{C}$	M	For vinyl examination gloves: ≥ 3.6	13	4.2	Passed

Table 3: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Size	Requirements	Result	Inferred Results
4.4 5.2	Powder-free gloves	L	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.16 mg per glove	Passed

REMARK:

- Lot number was not provided by client.

Yeo Poh Kwang
 Associate Engineer

Wong Bee Hui
 Product Manager
 Medical Health Services (NAM)

APPENDIX:



Photo: Disposable Vinyl/Nitrile Blend Examination Gloves



Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011



Test Report No. 7191237837-EEC20/02-WBH
dated 10 Jun 2020



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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Gloves submitted by Shijiazhuang Hongray Group Co., Ltd
on 21 May 2020.

TESTED FOR:

Shijiazhuang Hongray Group Co., Ltd
South Tongda Rd., East Dist.,
Jinzhou City, Hebei,
052260, China

TEST DATE:

04 Jun 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Lot No.	Colour	Size
1	Disposable Vinyl/Nitrile Blend Examination Gloves	- (See Remark 1)	Blue	XS
				S
				M
				L
				XL

METHOD OF TEST:

The tests were conducted in accordance with the following standards as requested by client:

1. EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 7 Labelling
2. EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation
-Clause 4.6 Labelling



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1 Science Park Drive, #02-01
Singapore 118221
TUV®

Test Report No. 7191237837-EEC20/02-WBH
dated 10 Jun 2020



RESULTS:

Sample: Disposable Vinyl/Nitrile Blend Examination Gloves

Table 1: Results for EN 455-2:2015 Clause 7


Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

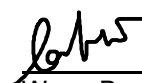
Table 2: Results for EN 455-3:2015 Clause 4.6

Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
Inferred results			Passed

REMARK:

1. Lot number was not provided by client.
2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter dated June 8, 2020.


Yeo Poh Kwang
Associate Engineer


Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo 1: Disposable Vinyl/Nitrile Blend Examination Gloves



Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011



Testing Report

Company Name: Grand Work Plastic Products Co., Ltd

Address: Donggao Industrial Zone, Zanhuan, Hebei, 050000, China

Test Date: Dec 06, 2019

Product Description: Powder Free Vinyl/Nitrile Blended Examination Gloves

Size: XS, S, M, L, XL

Test Standards: EN 455-1:2000 Medical Gloves for Single Use-Part 1: Requirements and Testing For Freedom from Holes
EN 455-2:2015 Medical Gloves for Single Use-Part 2: Requirements and Testing For Physical Properties
EN 455-3:2015 Medical Gloves for Single Use-Part 3: Requirements and Testing For Biological Evaluation Clause 4.4 & 4.6

Specification:

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		$\geq 240\text{mm}$	13 pieces, median
Width (mm)		XS: ≤ 80	13 pieces, median
		S: 80 ± 10	13 pieces, median
		M: 95 ± 10	13 pieces, median
		L: 110 ± 10	13 pieces, median
		XL: ≥ 110	13 pieces, median
Thickness (mm)	Middle Fingertip t^f	$t^f/t^x \geq 0.9$	13 pieces
	Test piece t^x		
Force at Break (N) (Before and After Aging)		$\geq 3.6\text{N}$	13 pieces, median
Water tightness		G-I, AQL1.5	200 pieces (Ac7, Re 8)
Powder		EN 455-3 Clause 4.4	$< 2\text{mg/glove}$
Labelling		EN 455-3 Clause 4.6	Conform to EN 455-3 Clause 4.6
Notes:			
1. Condition of sampling testing: Temperature: $23 \pm 2^\circ\text{C}$, Humidity: $50 \pm 5\%$			
2. Specimen shall be conditioned at least 16 hours before testing.			
3. Challenge testing condition: seven days at a temperature of $70 \pm 2^\circ\text{C}$ in an oven.			

Test Results: Please refer to the follows

Testing Report

1. Dimensions and Physical Properties

Test Standard and Method: EN 455-2

Test Condition: 22°C, 51%

Tested by: Ma Huina

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)	
			Test Piece	Middle Fingertip		Before Aging	After Aging
1	XS	242	0.08	0.09	76	3.8	3.8
2	XS	241	0.08	0.09	77	3.5	3.9
3	XS	242	0.08	0.09	76	3.6	3.6
4	XS	240	0.08	0.09	76	3.9	3.8
5	XS	240	0.08	0.09	75	3.7	3.8
6	XS	242	0.08	0.10	76	3.5	3.7
7	XS	245	0.08	0.10	76	3.8	3.6
8	XS	244	0.08	0.09	76	3.6	3.5
9	XS	242	0.08	0.09	76	3.5	3.8
10	XS	243	0.08	0.09	76	3.7	3.8
11	XS	240	0.08	0.09	75	3.6	3.7
12	XS	241	0.08	0.10	76	3.7	3.5
13	XS	243	0.08	0.09	75	3.8	3.9
Median Value		242	0.08	0.09	76	3.8	3.8
Test Result		Pass					
1	S	240	0.08	0.10	86	3.8	3.7
2	S	241	0.08	0.10	86	3.9	3.8
3	S	242	0.08	0.09	85	3.9	3.9
4	S	241	0.08	0.09	86	3.7	3.6
5	S	240	0.08	0.09	86	3.6	3.8
6	S	242	0.08	0.09	86	3.8	3.4
7	S	242	0.08	0.09	86	3.7	3.8
8	S	244	0.08	0.09	85	3.7	3.8
9	S	241	0.08	0.09	86	4.0	3.9
10	S	240	0.08	0.09	86	3.8	3.6
11	S	241	0.08	0.09	86	3.7	3.7
12	S	244	0.08	0.10	86	3.6	3.8
13	S	242	0.08	0.09	86	3.8	3.6
Median Value		241	0.08	0.09	86	3.8	3.8
Test Result		Pass					

Testing Report

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)	
			Test Piece	Middle Fingertip		Before Aging	After Aging
1	M	242	0.08	0.09	96	3.9	3.7
2	M	241	0.08	0.10	96	3.6	3.8
3	M	243	0.08	0.09	96	3.7	3.9
4	M	241	0.08	0.09	96	3.8	3.6
5	M	240	0.08	0.10	95	3.5	3.5
6	M	242	0.08	0.09	97	3.7	3.8
7	M	240	0.08	0.09	97	3.8	3.6
8	M	244	0.08	0.10	96	3.6	3.8
9	M	243	0.08	0.10	96	3.9	3.9
10	M	243	0.08	0.09	96	3.4	3.7
11	M	241	0.08	0.10	96	3.8	3.6
12	M	240	0.08	0.10	96	3.8	3.8
13	M	240	0.08	0.10	96	3.9	3.9
Median Value		241	0.08	0.10	96	3.8	3.8
Test Result		Pass					
1	L	242	0.08	0.10	105	3.8	3.8
2	L	241	0.08	0.09	105	3.9	3.9
3	L	243	0.08	0.09	106	3.7	3.6
4	L	241	0.08	0.10	105	3.5	3.8
5	L	243	0.08	0.10	105	3.6	3.5
6	L	242	0.08	0.10	107	3.5	3.8
7	L	242	0.08	0.09	106	4.0	3.6
8	L	244	0.08	0.09	106	3.8	3.5
9	L	242	0.08	0.10	106	3.6	3.8
10	L	240	0.08	0.09	107	3.6	3.6
11	L	242	0.08	0.09	106	4.0	3.6
12	L	241	0.08	0.10	106	3.8	3.8
13	L	242	0.08	0.10	106	3.9	3.9
Median Value		242	0.08	0.10	106	3.8	3.8
Test Result		Pass					
1	XL	244	0.08	0.10	117	3.9	3.9
2	XL	241	0.08	0.09	116	3.7	3.5
3	XL	243	0.08	0.09	116	3.7	3.8
4	XL	243	0.08	0.10	116	3.8	3.6

Testing Report

5	XL	243	0.08	0.10	115	3.8	3.5
6	XL	244	0.08	0.10	116	3.6	3.8
7	XL	242	0.08	0.09	116	3.8	3.6
8	XL	244	0.08	0.09	116	3.9	3.8
9	XL	243	0.08	0.10	116	3.5	3.8
10	XL	242	0.08	0.09	117	3.6	3.6
11	XL	243	0.08	0.09	117	3.8	3.9
12	XL	240	0.08	0.09	116	3.6	3.8
13	XL	242	0.08	0.10	116	4.0	3.7
Median Value		243	0.08	0.09	116	3.8	3.8
Test Result		Pass					

2. Watertightness test

Test Standard and Method: EN 455-1

Sample Size: ISO2859, Inspection Level: G-1, AQL=1.5, 200pcs (Ac=7, Re=8)

Tested by: An Lijuan Ma Huina

Size	Sample Count (pcs)	Pinhole (pcs)	Test Result
XS	200	2	Pass
S	200	2	Pass
M	200	1	Pass
L	200	2	Pass
XL	200	3	Pass

3. Powder and Labeling

Test Standard and Method: EN 455-3 clause 4.4 &4.6

Sample Size: 5 pieces of gloves were sampled.

Tested by: Ma Huina

Size	Average Powder (mg/glove)	Labelling	Test Result
XS	0.40	Pass	Pass
S	0.41	Pass	Pass
M	0.43	Pass	Pass
L	0.45	Pass	Pass
XL	0.47	Pass	Pass

Conclusion:

The Powder Free Vinyl/Nitrile Blended Examination Gloves met the test requirements EN 455-1, EN 455-2 and EN455-3 Clause 4.4 &4.6.

Signed By: *zhang Li*

Quality Manager

SHIJIAZHUANG HONGRAY GROUP

South Tongda Rd., East Dist. Jinzhou City, Hebei, 052260, China

TEL: 86-311-66179668

FAX: 86-311-66179676

www.hongray.com

SPECIFICATION FOR VINYL/NITRILE BLEND

EXAMINATION GLOVE

1.0 Product: Vinyl/Nitrile Blend, Powder Free, 9" length, for examination use

2.0 Dimensions:

Size	Median Length (mm)	Median Width (mm)	Thickness (mm) (min)	
			Palm	Finger
XS	240	75 ± 5	0.08	0.08
S	240	85 ± 5	0.08	0.08
M	240	95 ± 5	0.08	0.08
L	240	105 ± 5	0.08	0.08
XL	240	115 ± 5	0.08	0.08

3.0 Strength:

Force at break: 3.6N (Median)

4.0 Water Leakage Testing:

For exam gloves, according to ISO2859, G-I, Single Sampling Plan, AQL1.5

5.0 Powder Residues:

For powder free gloves, not more than 2mg per glove.

DOCUMENT NO.: PVC-014E

INITIALED DATE: 2005.04.12

REVISION DATE: 2020.01.06

REVISION TIMES: 7



中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：冀石药监械出 20200017

Certificate NO.: Certificate of medical device exports made in shijiazhuang
issued by Hebei Drug Supervision Administration No. 20200017

产品名称：详见附表

Product(s): Details as per attached list.

规格型号：详见附表

Model: Details as per attached list.

产品注册或备案凭证号：详见附表

Registration certificate(s): Details as per attached list.

生产企业：石家庄鸿锐集团有限公司

Manufacturer: Shijiazhuang Hongray Group Co., Ltd

生产企业住所：河北省晋州市通达路东段路南；河北省赞皇县东高工业园区；河北省
深泽县工业园区（府前西路）

Address of manufacturer: South Tongda Rd., East Dist. Jinzhou City, CHINA
052260; Donggao Industrial Zone Zanhuang, Hebei, China 050000; Fuqian Xi
Road, West district of Shenze Industrial Base, Shenze County, Hebei
Province, CHINA 050000

生产许可或备案凭证号：冀石食药监械生产备 20150008 号

Manufacturing License(s): medical device on file under Shijiazhuang Food
and Drug Supervision Administration, Hebei Province No. 20150008

兹证明上述产品已准许在中国生产和销售。 This is to certify that the
above products have been registered to be manufactured and sold in
China.

证明有效日期至： 2022 年 03 月 16 日

This certification valid until: Mar.16,2022

备注：

Remark:

2020 年 03 月 17 日



附表

序号	产品名称 中文 /Chinese	产品名称英文 /English	规格型号 中文 /Chinese	规格型号 英文 /English	注册证号 中文 /Chinese	注册证号英文 /English
2	一次性使用 医用 PVC 手套	disposable vinyl examination gloves	本产品分非 消毒和经环 氧乙烷消毒 型两种。非 消毒型分为： XS、S、M 、L、XL 100 只/盒 10 盒/箱、 50 只/盒 10 盒/箱、2 只 /袋 50 袋/ 小箱 10 小 箱/大箱； 消毒型分： XS、S、M 、L、XL 2 只/袋 50 袋/小箱 10 小箱/大箱、 2 只/袋 100 袋/小箱 10 小箱/大箱、 2 只/袋 125 袋/小箱 4 小箱/大箱、 1 只/袋 200 袋/小箱 10 小箱/大箱、 1 只/袋 100 袋/小箱 10 小箱/大箱。 按表面型式 分为两种， 有粉表面和 无粉表面。 有粉手套的	This product includes two types: Non- sterile and Sterilize by ETO. Non- sterile products include 5 Sizes: XS, S, M, L and XL; 100pcs/bo x and 10boxes/c ase; 50pcs/box and 10boxes/c ase; 2pcs/bag, 50bags/ca se and 10cases/m aster case. Sterile products include 5 Sizes: XS, S, M, L and XL; 2pcs/bag,	冀石械备 20150025 号	Registration of Medical Devices filed by Shijiazhuang Food and Drug Supervision Administration No.20150025

			<p>表面处理剂是玉米淀粉。按长度不同分为 9" 和 12" 两种。</p>	<p>50bags/case and 10cases/master case; 2pcs/bag, 100bags/case and 10cases/master case; 2pcs/bag, 125bags/case and 4cases/master case; 1pcs/bag, 200bags/case and 10cases/master case; According to the surface process method, there are two types of gloves (Powder Free and Pre-powdered). The surface treatment agent for Pre-powdered gloves is corn starch. There are two types of gloves which 9" and 12" by length.</p>	
--	--	--	--	--	--

1	一次性使用 医用丁腈手 套	disposable nitrile examination gloves	<p>本产品分非 消毒和经环 氧乙烷消毒 型两种。非 消毒型分为： XS、S、M 、L、XL 100 只/盒 10 盒/箱、 50 只/盒 10 盒/箱、2 只 /袋 50 袋/ 小箱 10 小 箱/大箱； 消毒型分： XS、S、M 、L、XL 2 只/袋 50 袋/小箱 10 小箱/大箱、 2 只/袋 100 袋/小箱 10 小箱/大箱、 2 只/袋 125 袋/小箱 4 小箱/大箱、 1 只/袋 200 袋/小箱 10 小箱/大箱、 1 只/袋 100 袋/小箱 10 小箱/大箱。 按表面型式 分为两种， 有粉表面和 无粉表面。 有粉手套的 表面处理剂 是玉米淀粉。 按长度不同 分为 9" 和 12" 两种。</p>	<p>This product includes two types: Non- sterile and Sterilize by ETO. Non- sterile products include 5 Sizes: XS, S, M, L and XL; 100pcs/bo x and 10boxes/c ase; 50pcs/box and 10boxes/c ase; 2pcs/bag, 50bags/ca se and 10cases/m aster case. Sterile products include 5 Sizes: XS, S, M, L and XL; 2pcs/bag, 50bags/ca se and 10cases/m aster case; 2pcs/bag, 100bags/c ase and 10cases/m aster case; 2pcs/bag, 125bags/c</p>	冀石械备 20150026 号	<p>Registration of Medical Devices filed by Shijiazhuang Food and Drug Supervision Administration No.20150026</p>
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				<p>ase and 4cases/ma ster case; 1pcs/bag, 200bags/c ase and 10cases/m aster case; Accordin g to the surface process method, there are two types of gloves (Powder Free and Pre- powdered). The surface treatment agent for Pre- powdered gloves is corn starch. There are two types of gloves which 9" and 12" by length.</p>		
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Test Report

No. TSNEC2000806611

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments— Overall migration	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.



Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806611

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.011	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
or EN 1186-3:2002 aqueous food simulants by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 011 Overall Migration</u>
3% Acetic Acid (W/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	<3.0mg/dm ²

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm².
- (2) Test condition & simulant were specified by client.
- (3) Report the first migration result.



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Date: 09 Jun 2020

Page 3 of 3

Sample photo:



SGS authenticate the photo on original report only

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Test Report

No. TSNEC2000806606

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments— Overall migration	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806606

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.006	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
or EN 1186-3:2002 aqueous food simulants by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 006 Overall Migration</u>
10% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	3.8mg/dm ²

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm².
- (2) Test condition & simulant were specified by client.
- (3) Report the first migration result.



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Date: 09 Jun 2020

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Test Report

No. TSNEC2000806607

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments— Overall migration	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806607

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.007	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments– Overall migration

Test Method : With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods;
or EN 1186-3:2002 aqueous food simulants by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 007 Overall Migration</u>
20% Ethanol (V/V) Aqueous Solution	2.0hr(s)	70°C	10mg/dm ²	4.2mg/dm ²

Notes :

- (1) Analytical tolerance of aqueous simulants is 2 mg/dm² .
- (2) Test condition & simulant were specified by client.
- (3) Report the first migration result.



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Test Report

No. TSNEC2000806601

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Vinyl chloride monomer	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806601

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.001	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Vinyl chloride monomer

Test Method : SGS In house method (SHTC-CHEM-SOP-171-T), analysis was performed by HS-GC-MS.

Test Item(s)	Limit	Unit	MDL	001
VCM(Vinyl Chloride Monomer)	1	mg/kg	0.5	ND
Conclusion				PASS

Notes :

- (1) The test was subcontracted to SGS Shanghai chemical lab.



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Test Report

No. TSNEC2000806610

Date: 09 Jun 2020

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SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Implementing Regulation (EU) 2018/213 of 12 February 2018 amending Regulation (EU) 10/2011 of 14 January 2011-Bisphenol A	PASS

Signed for and on behalf of
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Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806610

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.010	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Implementing Regulation (EU) 2018/213 of 12 February 2018 amending Regulation (EU) 10/2011 of 14 January 2011-Bisphenol A

Test Method : With reference to Part II Section D2 of Testing Methods for Foodstuffs, Implements, Containers and Packaging, Toys, Detergents, JETRO, Japan External Trade Organization, 2009 (Dichloromethane extraction by ultrasonic bath). Analysis was performed by LC/MSMS.

Test Item(s)	Limit	Unit	MDL	010
Bisphenol-A	★	mg/kg	0.1	ND
Conclusion				PASS

Notes :

- (1) ★=prohibited



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Test Report

No. TSNEC2000806610

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Test Report

No. TSNEC2000806605

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Page 1 of 3

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SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Bisphenol A	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

Reabeca Zhou
Approved Signatory



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Test Report

No. TSNEC2000806605

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.005	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Specific Migration of Bisphenol A

Test Method : With reference to EN13130-1:2004, analysis was performed by HPLC-FLD.

Sample 005

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 70 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of Bisphenol-A	0.05	mg/kg	0.01	ND

Notes :

- (1) Test condition & simulant were specified by client.



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Test Report

No. TSNEC2000806605

Date: 09 Jun 2020

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Sample photo:



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Test Report

No. TSNEC2000806602

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Phthalates	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.

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Test Report

No. TSNEC2000806602

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.002	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Phthalates

Test Method : Solvent extraction, analysis was performed by GC-MS.

Test Item(s)	CAS NO.	Limit	Unit	MDL	002
Dibutyl Phthalate (DBP)	84-74-2	0.05	% (w/w)	0.003	ND
Benzylbutyl Phthalate (BBP)	85-68-7	0.1	% (w/w)	0.003	ND
Bis-(2-ethylhexyl) Phthalate (DEHP)	117-81-7	0.1	% (w/w)	0.003	0.006
Diisononyl Phthalate (DINP)	28553-12-0/ 68515-48-0	0.1	% (w/w)	0.01	ND
Diisodecyl Phthalate (DIDP)	26761-40-0/ 68515-49-1	0.1	% (w/w)	0.01	ND



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Test Report

No. TSNEC2000806602

Date: 09 Jun 2020

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Sample photo:



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Test Report

No. TSNEC2000806609

Date: 09 Jun 2020

Page 1 of 3

SHIJIAZHUANG HONGRAY GROUP CO., LTD.
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI
052260, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE VINYL/NITRILE BLEND EXAMINATION GLOVES

SGS Job No. : TP20-003330 - TJ
Model No. : M
Client Ref. Info. : Other Model No.:XS,S,M,L,XL,XXL
Date of Sample Received : 22 May 2020
Testing Period : 22 May 2020 - 04 Jun 2020
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments – Specific Migration of Heavy Metal	PASS

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Tianjin) Co., Ltd.



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Test Report

No. TSNEC2000806609

Date: 09 Jun 2020

Page 2 of 3

Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	TSN20-008066.009	blue gloves	Vinyl/Nitrile Blend

Remarks :

- (1) mg/dm² = milligram per square decimeter
- (2) mg/kg = milligram per kilogram
- (3) °C= degree Celsius
- (4) < = less than
- (5) MDL = Method Detection Limit
- (6) ND = Not Detected (< MDL)

Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments –Specific Migration of Heavy Metal

Test Method : With reference to EN13130-1:2004, analysis was performed by ICP-OES.

Sample 009

Simulant Used : 3% Acetic Acid (W/V) Aqueous Solution

Test Condition : 70 °C 2.0 hr(s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Barium	1	mg/kg	0.25	ND
Cobalt	0.05	mg/kg	0.01	ND
Copper	5	mg/kg	0.25	ND
Iron	48	mg/kg	0.25	ND
Lithium	0.6	mg/kg	0.5	ND
Manganese	0.6	mg/kg	0.25	ND
Zinc	5	mg/kg	0.5	ND
Aluminium	1	mg/kg	0.1	ND
Nickel	0.02	mg/kg	0.01	ND

Notes :

- (1) Test condition & simulant were specified by client.



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Sample photo:



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[Übersicht](#)[Medizinprodukte](#)[In-vitro-Diagnostika](#)[Klinische Prüfungen](#)[Adresse](#)[Firmenfusion](#)[Neu](#)

Produkt

Produkttyp	nichtaktives Medizinprodukt
Klasse	I
App (Software auf mobilen Endgeräten)	Nein
Tragen alle Medizinprodukte eine CE-Kennzeichnung und werden innerhalb ihrer Zweckbestimmung eingesetzt?	—

Medizinprodukt

Handelsname	Disposable Vinyl/Nitrile Blend Examination Gloves
Allgemeine Produktbezeichnung	—
Nomenklaturcode	11-882
Nomenklaturbezeichnung	Handschuh, Untersuchung/Behandlung
Kategorie	Produkte zum Einmalgebrauch
Kurzbeschreibung in Deutsch	Der Handschuh ist ein nicht steriles Einweggerät für medizinische Zwecke, das an der Hand des Untersuchers getragen wird, um eine Kontamination zwischen Patient und Prüfer zu verhindern.
Kurzbeschreibung in Englisch	The glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner.

1. Hersteller

Bezeichnung	Shijiazhuang Hongray Group Co., Ltd.
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Ort	Jinzhou
Postleitzahl	052260
Strasse	South Tongda Rd., East Dist.
Telefon	0311-83610904
Telefax	0311-83610904
E-Mail	—



FDA ANNUAL REGISTRATION INFORMATION

Name: Grand Work Plastic Products Co., Ltd.

Address: Donggao Industrial Zone, Zhanhuang, Hebei, 050000, China

The factory has completed the Establishment Registration and Device Listing with the US Food & Drug Administration for 2020 and the registration will be valid through Dec 31, 2020.

Registration Number: 3004168786

Current Status: Active

Products: Vinyl Co-Polymer Powder-free Examination Gloves (Disposable Vinyl/Nitrile Blend Examination Gloves)

Product Code: 80 LYZ

Regulatory Class: Class I

Holds 510(k) premarket notification

All information is available at the following address:

<https://www.fda.gov/>

Date of Verification: Oct 10, 2019

Date of Expiration: Dec. 31, 2020



Consumer Product Testing Co.

FINAL REPORT

CLIENT:

Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone
Zanhuang, Hebei, China 050000

AUTHORIZING AGENT:

Kathy Liu

TEST:

Primary Dermal Irritation in Rabbits (ISO)

TEST ARTICLE:

Vinyl Co-Polymer Powder Free Examination Gloves,
Blue Color; Size: M; Lot#: 1405F4A3-PF

**EXPERIMENT
REFERENCE NUMBER:**

T14-2583-1

Steven Nitka
Vice President
Laboratory Director

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Consumer Product Testing Co.

QUALITY ASSURANCE UNIT STATEMENT

Study No.: T14-2583-1

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and accurate reporting of non-clinical laboratory studies. This study has been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance with CPTC Standard Operating Procedures (SOP's) and applicable standard protocols. The QAU maintains copies of study protocols and SOP's and has inspected this study on the date(s) indicated below. The findings of these inspections have been reported to CPTC Management and the Study Director.

Date(s) of inspection(s): 6/6/14, 7/8/14, 8/12/14

Date(s) finding(s) reported to CPTC Management and the Study Director: 7/15/14

Quality Unit Certified By Christine Hendrick Date: 8/13/14



Consumer Product Testing Co.

EST. 1975

Final Report Summary

CLIENT: Grand Work Plastic Products Co., Ltd.

STUDY NO.: T14-2583-1

REFERENCE: K. Liu

TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M;
Lot#: 1405F4A3-PF

TEST ARTICLE RECEIPT DATE: May 23, 2014

EXPERIMENTAL INTERVAL: July 8, 2014 to July 22, 2014

Primary Dermal Irritation in Rabbits (ISO)

Method: Three (3) New Zealand White rabbits each received a single dermal application of 25 mm x 25 mm of the test article on two (2) test sites, both non-abraded. Each animal also had two (2) control sites. The negative control site consisted only of gauze moistened with physiological saline. The positive control site consisted of a dosage of sodium dodecyl sulfate at two and one-half (2.5) percent. The test sites were semi-occluded for four (4) hours and were observed individually for erythema, edema, and other effects one (1), 24, 48 and 72 hours after unwrapping. If irritation persisted, the sites were observed again on days seven (7) and fourteen (14). The primary irritation index was determined as detailed on page six (6) of this report. The test article, in one (1) inch squares, was moistened with distilled water upon dosing and applied so that the inside of the glove test article contacted the skin of three (3) test sites and the outside of the glove test article contacted the skin of the remaining three (3) test sites.

Results: Primary Irritation Indices:*

0.00 (Test Article)
2.77 (Positive Control)
0.00 (Negative Control)

Conclusion: This test article elicited a negligible dermal response in rabbits under the conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits (ISO)

Objective:

This test was designed to assess the potential of the test article to produce irritation on rabbit skin according to the International Organization for Standardization standards.¹

Test Article:

The test article arrived at this facility as blue gloves. The intended use and/or application of the test article is thought, by this facility, to be that of standard examination gloves.

Test System:

Three (3), female, New Zealand White rabbits, about three (3) months of age, weighing at least two (2) kilograms, were used for the test article. The animals were obtained through a suitably licensed dealer. They were of a single strain from a single recognized source. They were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, skin lesions, and general condition.

The animals were acclimated for at least 13 days prior to test initiation. They were individually housed in stainless steel cages, in a temperature controlled room, with a 12 hour light/dark cycle and identified through individual markings on the outer ear of each animal, as well as a cage label. The room temperature was controlled to comply with Animal Welfare Regulations with an approximate range of 65° to 72° F. The humidity was also monitored. Diet consisted of Lab Diet Certified High Fiber Diet #5325 at 100 grams per day per animal. Water was provided *ad libitum*. There are no known contaminants that are reasonably expected to be present in animal feed or water at levels sufficient to interfere with this study.

Method:

The study director did not anticipate a well-defined irritation response from the test article, therefore one (1) animal was not dosed initially. Three (3) animals were dosed in the following manner:

¹The International Organization for Standardization (ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, Reference Number ISO 10993-10:2010)

Method (continued):

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition and particularly animals with skin eruptions or dermal lesions, were not used. The animals were prepared for testing by close-clipping the hair of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using an Oster® small animal clipper equipped with a #40 (surgical) head. Care was taken to avoid abrasion of the skin during clipping. The following day, initial weights were recorded for each animal.

For the test article, samples 25 mm by 25 mm were applied directly to the skin on each side of each rabbit (see Figure 1). The negative control (physiological saline at 100%) and the positive control (sodium dodecyl sulfate, at two and one-half (2.5) percent in physiological saline) were applied, each on one (1) site of each animal, in an identical manner (Figure 1). The test article was moistened sufficiently with distilled water, to ensure good contact with the skin. The sites were then covered by 25 millimeter by 25 millimeter, gauze sponges and a Kendall Webril® pad. Three (3) inch 3M Micropore™ tape was used to wrap the sites semi-occlusively. Elizabethan collars were used to preclude the animals from interfering with the articles and wrapping.

The wrapping was removed four (4) hours following application and the position of the sites were marked on the skin. Residual article was removed by appropriate means. The sites were then carefully dried.

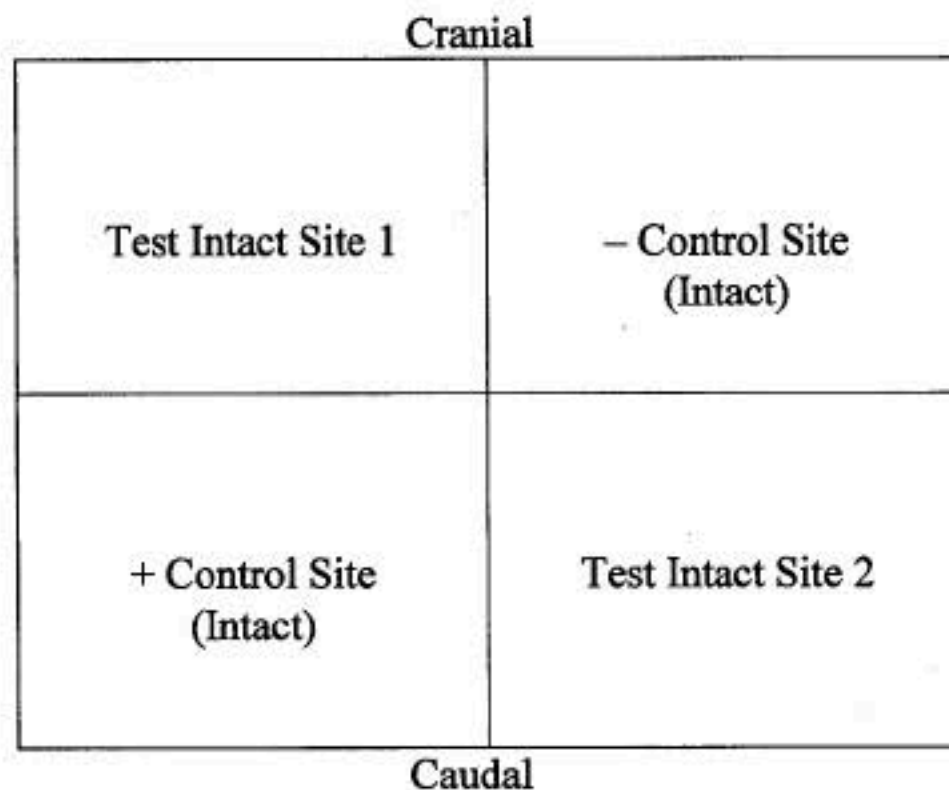


Figure 1 – Location of Skin Application Sites

Method (continued):

Each test site was scored individually 60 minutes after unwrapping, for erythema and edema using the Draize skin scoring scale (refer to the appended table). Test sites were re-examined 24, 48 and 72 hours after unwrapping for the same parameters. The presence of effects not listed in the scoring scale, such as fissuring, ulceration, vesiculation, etc., were noted separately if observed. Observation continued until all irritation subsided or irritation present was confirmed to be irreversible (14 days maximum).

The Primary Irritation Index was determined for the test article as follows:

Only the 24, 48 and 72 hour scores were used in these calculations. For each animal, the Primary Irritation Scores for the test article for both erythema and edema at each time specified were added together. This sum was then divided by the total number of observations (six (6): two (2) sites at each time specified). As a negative control was used, the Primary Irritation Score for the negative controls was also calculated. That score was subtracted from the score for the test article to obtain the Primary Irritation Score for each animal.

The scores for each animal were then added together. This sum was divided by the total number of animals. The resultant figure was the Primary Irritation Index. Observations made prior to 24 hours or after 72 hours, to monitor recovery, were not used in this determination.

Record Retention:

All records and documents pertaining to the conduct of this study shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QA Department to obtain custody of study records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, study-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Professional personnel involved:

Steven Nitka, B.S.	- Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	- Laboratory Supervisor
Christine Hendricks	- Quality Assurance Group Leader

Primary Dermal Irritation in Rabbits (ISO)

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

ERYTHEMA FORMATION	
<hr/>	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
<i>Total possible erythema score = 4</i>	
<hr/>	
EDEMA FORMATION	
<hr/>	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (area raised more than 1 mm and extending beyond area of exposure)	4
<i>Total possible edema score = 4</i>	
<hr/>	
Total possible primary irritation score = 8	
<hr/>	

Table 2

Dermal Irritation Response Categories in the Rabbit

Response Category	Mean Score
Negligible	0.0 to 0.4
Slight	0.5 to 1.9
Moderate	2.0 to 4.9
Severe	5.0 to 8.0

Table 3

Primary Skin Irritation – Rabbit

Summary of Scores for Skin Irritation

**Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color;
Size: M; Lot#: 1405F4A3-PF**

Dose = 25 mm x 25 mm (moist with distilled water)							Date: 7/8/14	
Animal # - Sex	Initial Wgt (kg)	T/C*	Scores @					
			1 Hr.	24 Hrs.	48 Hrs.	72 Hrs.	Day 7	Day 14
1 (111F)	2.31	T(I)	0/0	0/0	0/0	0/0	0/0	---
		T(I)	0/0	0/0	0/0	0/0	0/0	---
		C ¹	0/0	0/0	0/0	0/0	0/0	---
		C ²	2/1	2/1	2/0	2/0	0/0S	---
2 (113F)	2.35	T(I)	0/0	0/0	0/0	0/0	0/0	0/0
		T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		C ¹	0/0	0/0	0/0	0/0	0/0	0/0
		C ²	2/2	2/1	2/1	2/1	1/0S	0/0
3 (123F)	2.11	T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		C ¹	0/0	0/0	0/0	0/0	0/0	0/0
		C ²	2/1	2/1	2/1	2/1S	1/0S	0/0S

Raw Data Page: 161791

Scores = Erythema/Edema

*T = Test article site; (I) = inside of glove contacted skin, (O) = outside of glove contacted skin

* C¹ = Negative control site (physiological saline at 100%)

* C² = Positive control site (sodium dodecyl sulfate, at two and one-half (2.5) percent in physiological saline)

All sites were intact

S = Scaling



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

CLIENT:

Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone
Zanhuang, Hebei, China 050000

AUTHORIZING AGENT:

Kathy Liu

TEST:

Guinea Pig Closed Patch Sensitization Test (ISO)

TEST ARTICLE:

Vinyl Co-Polymer Powder Free Examination Gloves,
Blue Color; Size: M; Lot#: 1405F4A3-PF

**EXPERIMENT
REFERENCE NUMBER:**

T14-2583-2

Steven Nitka
Vice President
Laboratory Director

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.



EST. 1975

Consumer Product Testing Co.

QUALITY ASSURANCE UNIT STATEMENT

Study No.: T14-2583-2

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and accurate reporting of non-clinical laboratory studies. This study has been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance with CPTC Standard Operating Procedures (SOP's) and applicable standard protocols. The QAU maintains copies of study protocols and SOP's and has inspected this study on the date(s) indicated below. The findings of these inspections have been reported to CPTC Management and the Study Director.

Date(s) of inspection(s): 6/6/14, 6/25/14, 8/12/14

Date(s) finding(s) reported to CPTC Management and the Study Director: 6/30/14

Quality Unit Certified By: Christine Hendrick Date: 8/13/14



Consumer Product Testing Co.

Final Report Summary

CLIENT: Grand Work Plastic Products Co., Ltd.

STUDY NO.: T14-2583-2

REFERENCE: K. Liu

TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M;
Lot#: 1405F4A3-PF

TEST ARTICLE RECEIPT DATE: May 23, 2014

EXPERIMENTAL INTERVAL: June 25, 2014 to July 30, 2014

Guinea Pig Closed Patch Sensitization Test (ISO)

Method: Ten (5M:5F) Hartley-strain guinea pigs, 320 - 358 grams, were utilized as the test group. An additional five (2M:3F) Hartley-strain guinea pigs, 302 - 366 grams, were utilized as the control group. For induction, each animal in the test group received nine (9), six (6) hour topical applications of the test article, made, up to three (3) times per week, during consecutive weeks. The control group animals were similarly dosed, but with the wrapping alone, moistened with physiological saline. Approximately two (2) weeks after the last topical induction application, the challenge application was made. These six (6) hour challenge applications of the test article were made to virgin sites on the flank of each animal in the test and control groups. Observations of erythema, edema and other effects were recorded 24 and 48 hours after the challenge applications. The test article was used as received and moistened with saline upon dosing and applied so that the inside of the glove test article contacted the skin of approximately one-half of the animals in each group and the outside of the glove test article contacted the skin of approximately one-half of the animals in each group.

Results:

Index: Group	Challenge	
	<u>Incidence Test/Control</u>	<u>Severity Test/Control</u>
Scoring Interval:		
24 Hours:	0.00/0.00	0.00/0.00
48 Hours:	0.00/0.00	0.00/0.00

Conclusion: This test article did not elicit a sensitization reaction in guinea pigs under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.

Severity Index = The sum of the erythema scores divided by the number of animals observed at challenge.

Guinea Pig Closed Patch Sensitization Test (ISO)

Objective:

This test was designed to assess the potential of a medical glove test article to produce skin sensitization in guinea pigs according to the International Organization for Standardization standards.¹ The method is essentially that of Buehler.^{2,3}

Test Articles:

The test article arrived at this facility as blue gloves. The intended use and/or application of the test article is thought, by this facility, to be that of standard examination gloves.

Test System:

Fifteen, albino, Hartley-strain guinea pigs, male and female, approximately four to six (4-6) weeks of age and between 300 and 500 grams at the start of the test, were used. The animals were obtained through a suitably licensed dealer. The number of animals and the species used are those specified in the quoted regulation. Guinea pigs have a history of use in topical sensitization testing. They were of a single strain from a single recognized source. They were carefully checked upon receipt and prior to test initiation for respiratory or intestinal disease, skin eruptions, mucosal membrane irritation, postural difficulties and general condition. Females were nulliparous and not pregnant. Guinea pig sensitization reactions are well documented in the scientific literature and guinea pigs have been used extensively in studies of this type.

The animals were acclimated for seven (7) days prior to test initiation. They were housed in stainless steel cages in a temperature controlled room with a 12 hour light/dark cycle and were identified through individual markings as well as a cage label. The room temperature was controlled to comply with USDHHS guide with an approximate range of 64° to 79° F. The humidity was also monitored. Diet consisted of Lab Diet Certified Guinea Pig Diet #5026, as well as water, *ad libitum*. There are no known contaminants that are reasonably expected to be present in animal feed or water at levels sufficient to interfere with this study.

¹The International Organization for Standardization (ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, Reference Number ISO 10993-10:2010)

²E.V. Buehler, "Delayed Contact Hypersensitivity in the Guinea Pigs," *Arch Derma*, 91, (1965), pp. 171 - 175.

³H.L. Ritz & E.V. Buehler, "Planning, Conduct and Interpretation of Guinea Pig Sensitization Patch Tests", in *Current Concepts in Cutaneous Toxicity*, V.A. Drill and P. Lazar, (Eds.), Academic Press 1980 pp. 25 - 41.

Method:

All shaving procedures were carried out the day prior to treatment using an Oster[®] small animal clipper equipped with a #40 (surgical) head. During all shaving procedures, care was taken to avoid abrading the skin.

SUMMARY

Because the test article was dosed as received, no screening procedures were carried out. The study had the following two (2) phases:

1. The induction phase, which consisted of nine (9), six (6) hour topical applications of the test article, made up to three (3) times per week during consecutive weeks, using the test group animals. Another group was also treated topically in the same manner, without the test article and served as a control for local irritation.
2. The challenge phase, which involved a single topical primary application of the test article, made to a naïve (previously untreated) site on the induced, test group animals and on the control group animals.

For each of the above mentioned phases of the study, the same test system, the same amount and method of test article application and the same method of test site observation were used.

INDUCTION

For induction, 15 guinea pigs were weighed. Ten (5M:5F) animals were used for the test group and five (2M:3F) animals were used for the control group. The animals were designated so that the inside of the glove test article would contact the skin of approximately one-half of the animals in each group and the outside of the glove test article would contact the skin of approximately one-half of the animals in each group. The sites and animals were then examined grossly. Animals showing dermal lesions, irritation, improper weight or ill health, were replaced. All animals were shaved at site 1 (Fig. 1). One (1) square inch of the test article (25 mm x 25 mm), moistened with saline, was applied to the shaven site one (1), on all animals in the test group. The article was applied to each site via a 25 mm Hilltop Chamber. The animals were occlusively wrapped after dosing, with a piece of three (3) inch Tensoplast[®] elastic tape (BSN medical S.A.S., Vibraye, France), that had been lined on the adhesive side with a three (3) inch wide strip of Hygenic[®] Dental Dam. The control group animals were similarly dosed but without the test article. They were exposed only to the Hilltop Chamber moistened with physiological saline under the occlusive wrap. The wraps were removed after six (6) hours of exposure. Approximately seven (7) and twenty-four hours after application, each test site was examined and scored.

CHALLENGE

Thirteen days after the ninth induction application, all animals in both groups were shaved on site 3. The next day, each test and control animal received a single occluded challenge application of the test article, prepared as in the induction phase, at site 3. The occlusive wrap, as previously stated, was removed after six (6) hours of exposure.

At 24 hours (± 2 hrs) after the challenge dosage, all challenge sites, as well as the surrounding areas, were shaved. After a minimum of two (2) hours after hair removal, each test site was examined and scored according to Table 1. The sites were again graded 48 hours (± 2 hrs) after removal of the challenge patch. For reporting purposes, the first and second gradings are designated as 24 and 48 hour readings respectively.

All animals appeared healthy and gained weight during the course of the study.

This facility will also be reporting the results of a positive control test conducted within six (6) months of this test. Initial and terminal body weights were recorded for all animals. All animals appeared healthy and gained weight during the course of the study.

Evaluation of Results:

Grades of one (1) or greater in the test group generally indicate sensitization, provided grades of less than one (1) are seen on control animals. If grades of one (1) or greater were noted on control animals, then the reactions of test animals which exceed the most severe control reaction would be presumed to be due to sensitization.

Two (2) indices were calculated from the challenge erythema scores, one (1) to evaluate the incidence of erythema (reaction) and the other to evaluate the severity of erythema. The indices for incidence and severity were calculated for both groups from all scoring intervals. The incidence index was calculated by counting the number of animals showing an erythema response (1 or greater), for a specified time period and by dividing that number by the number of test sites (animals) examined at that time period (# responses/# per group). The severity index was calculated by adding the erythema scores for a specified time period and dividing that sum by the number of scores added (sum of irritation scores/# scores added). The two (2) indices were used to assist in evaluating the sensitization potential of the test article.

Record Retention:

All records and documents pertaining to the conduct of this study shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QA Department to obtain custody of study records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, study-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Guinea Pig Closed Patch Sensitization Test (ISO)

The scoring scale used is presented in Table 1. The site configuration is presented in Figure 1. Individual test group results are presented in Table 2. Individual control group results are presented in Table 3.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Professional personnel involved:

Steven Nitka, B.S.	-	Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	-	Laboratory Supervisor
Christine Hendricks	-	Quality Assurance Group Leader

Summaries of all results are found preceding the text.

TABLE 1

**Scoring Criteria for Skin Reactions
Magnusson and Kligman Scale**

<u>Patch Test Reaction</u>	<u>Grading Scale</u>
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
<u>Intense erythema and swelling</u>	<u>3</u>

FIGURE 1
GUINEA PIG SENSITIZATION

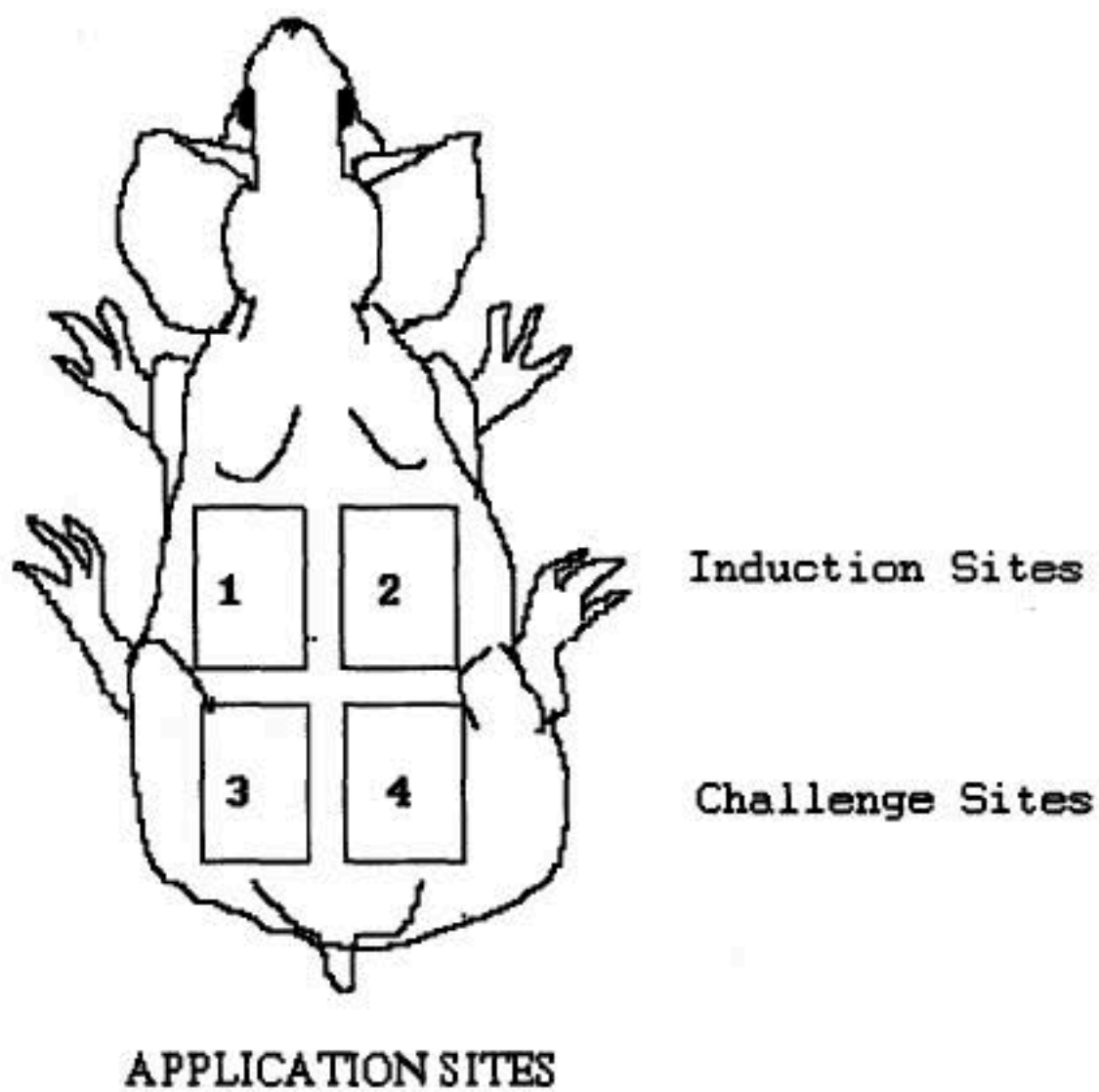


Table 2

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Test Group

Dosage: 1 sq", moist w/saline, using a 25 mm Hilltop Chamber

		Animal Number/Sex				
		1M	2M	3M	4M	5M
Initial Bdwts. (grams):		358	320	344	342	334
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		568	542	572	600	596

Raw Data Page: 161753

Animals #1 -3 were exposed to the inside of the glove and #4 - 5 were exposed to the outside of the glove.

Table 2 (continued)

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Test Group						
Dosage: 1 sq", moist w/saline, using a 25 mm Hilltop Chamber						
	Time After Application	Animal Number/Sex				
		6F	7F	8F	9F	10F
Initial Bdwts. (grams):		350	348	350	346	332
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		512	564	544	552	516

Raw Data Page: 161753

Animals #6 -7 were exposed to the inside of the glove and #8 - 10 were exposed to the outside of the glove.

Table 3

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Control Group

Dosage: Induction - saline blank using a 25 mm Hilltop Chamber

Challenge - 1 sq" test article, moist w/saline, using a 25 mm Hilltop Chamber

		Animal Number/Sex				
		1M	2M	3F	4F	5F
Initial Bdwts. (grams):		362	356	302	354	366
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		700	628	462	510	532

Raw Data Page: 161754

Animals #1, 3 & 4 were exposed to the inside of the glove and #2 & 5 were exposed to the outside of the glove.

Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0298451/2022/EN
Unit 110, Xinzhongyin Garden /C
Hongwei Road STE Job number: CHT0298236
Xiping, Nancheng District Date of report: 22nd July 2020
DONGGUAN CITY Samples received: 26th May 2020
Guangdong Province Date(s) work carried out: 13th to 20th July 2020
China
523079

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei 052260
China

Subject: Testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens on gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black).

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Emma Norris
Position: Technologist Team Leader
Department: Chemical & Analytical Technology



WORK REQUESTED:

Samples of gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black) were received on the 26th May 2020 for testing in accordance with ISO 16604:2004 to meet the requirements of EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage. Testing was completed at an external laboratory and reported under their reference 20RA07408.

SAMPLE SUBMITTED



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue)



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Green)



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Black)

TESTING REQUIRED:

- ISO 16604:2004 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage

RESULTS:

The positive control sample showed the bacteriophages passed through a microporous film whilst the negative control samples showed no passage through the polyethylene film.

Test specimen	Result	Pass/Fail
1	No penetration	Pass
2	No penetration	Pass
3	No penetration	Pass

APPENDICES:

Resistance to penetration by blood-borne pathogens-Test method using Phi-X174 bacteriophage

Standard used	ISO 16604 (2004)
Product standard	EN ISO 374-5 (2016)
Dimension of the test specimens	75mm x 75mm
Number of test specimens	3
Test procedure used	Procedure B
Used bacteriophage	<i>Bacteriophage Phi-X174 (ATCC 13706-B1 LOT CNCM 14812)</i>
Penetration survey method	Plaque-forming units (PFU)
Pre-test bacteriophage titre	7.0×10^8 PFU/ml
Post-test bacteriophage titre	6.9×10^8 PFU/ml

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing.
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an 'as new' condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licences or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0298451/2022/LH
Unit 110, Xinzhongyin Garden /A
Hongwei Road Your reference: CHT0298236
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079
Date of report: 17th June 2020
Samples received: 26th May 2020
Date(s) work carried out: 4th to 10th June 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei 052260
China

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black)

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

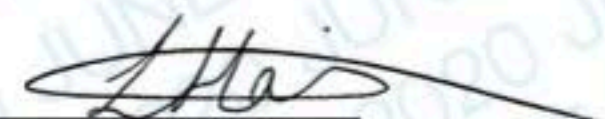
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked # fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology



WORK REQUESTED:

Samples of gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black) were received on the 26th May 2020 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

SAMPLES SUBMITTED:



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue)

Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Green)

Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Black)

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black) achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	6
37% Formaldehyde (CAS: 50-00-0)	6

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

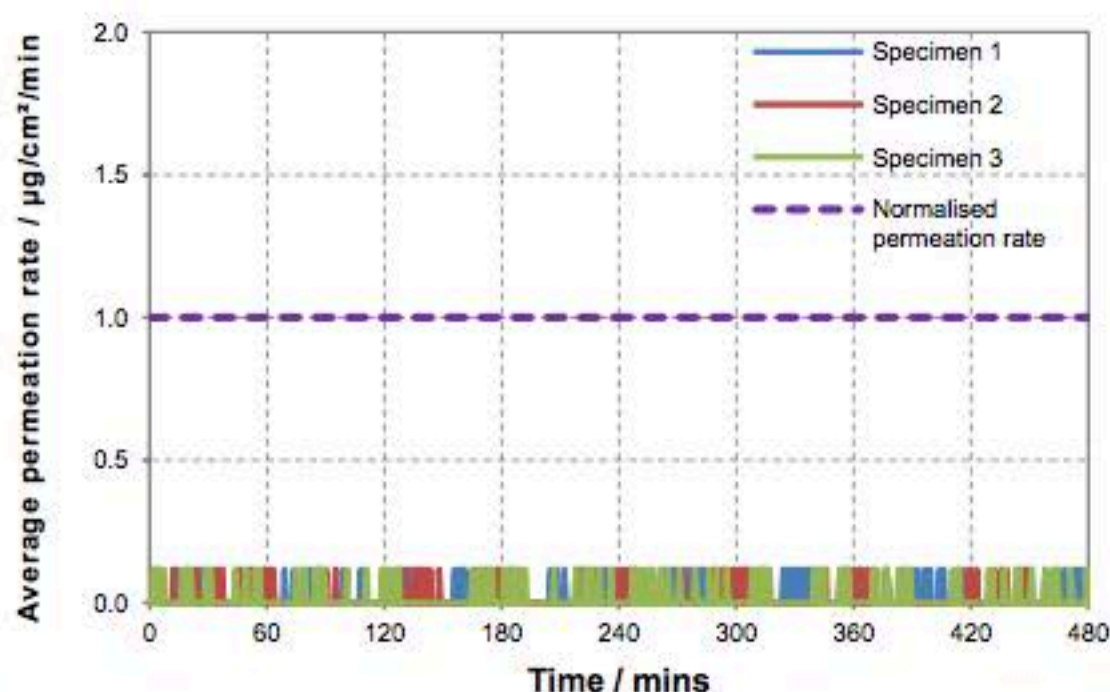
EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

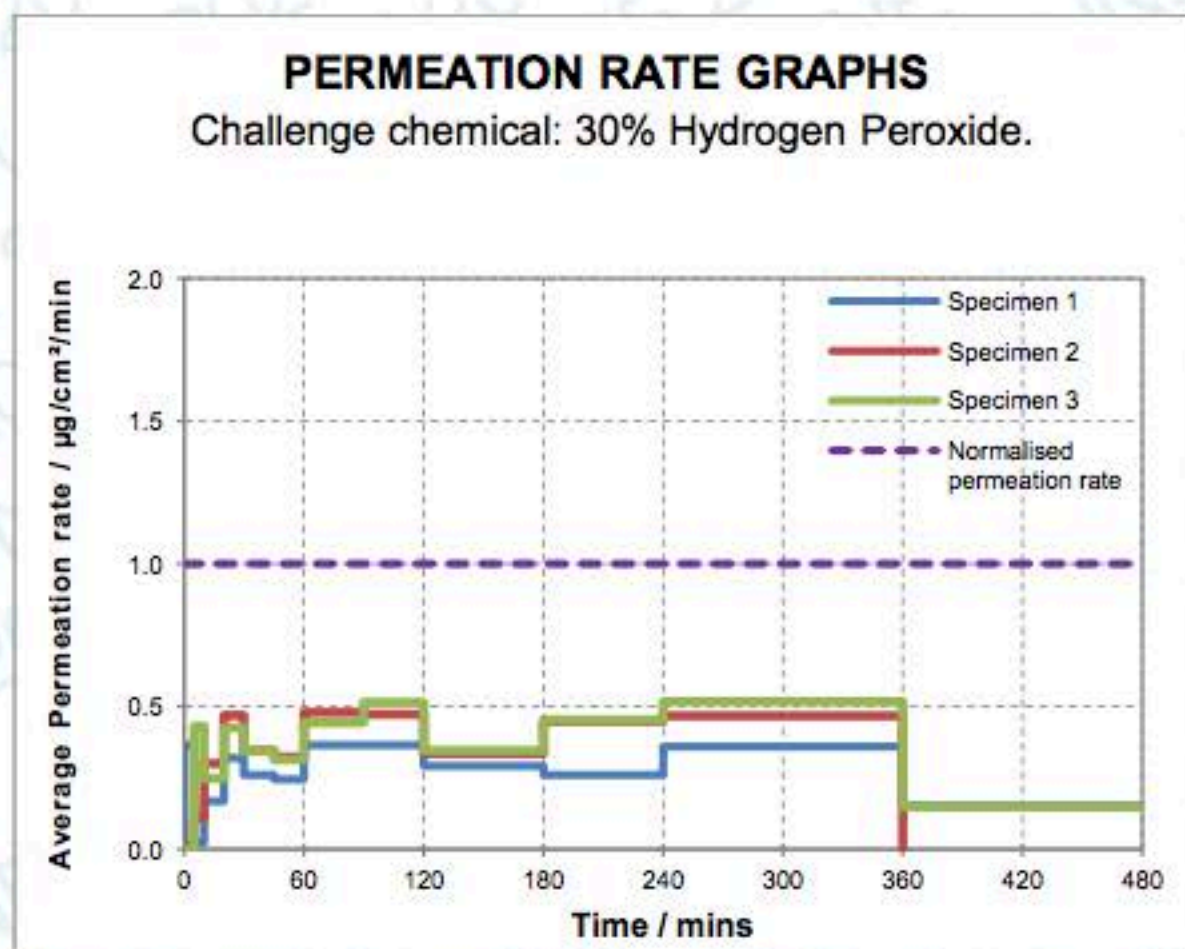
Performance levels are based on the lowest individual result achieved per chemical.

Test/Property	Sample reference:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)△	Breakthrough time (mins)	
		1 (Blue)	>480	
		2 (Green)	>480	
		3 (Black)	>480	
			Test result: >480	
		UoM: < 1		
Visual appearance of specimens after testing:		No change		

PERMEATION RATE GRAPHS
Challenge chemical: 40% Sodium Hydroxide.

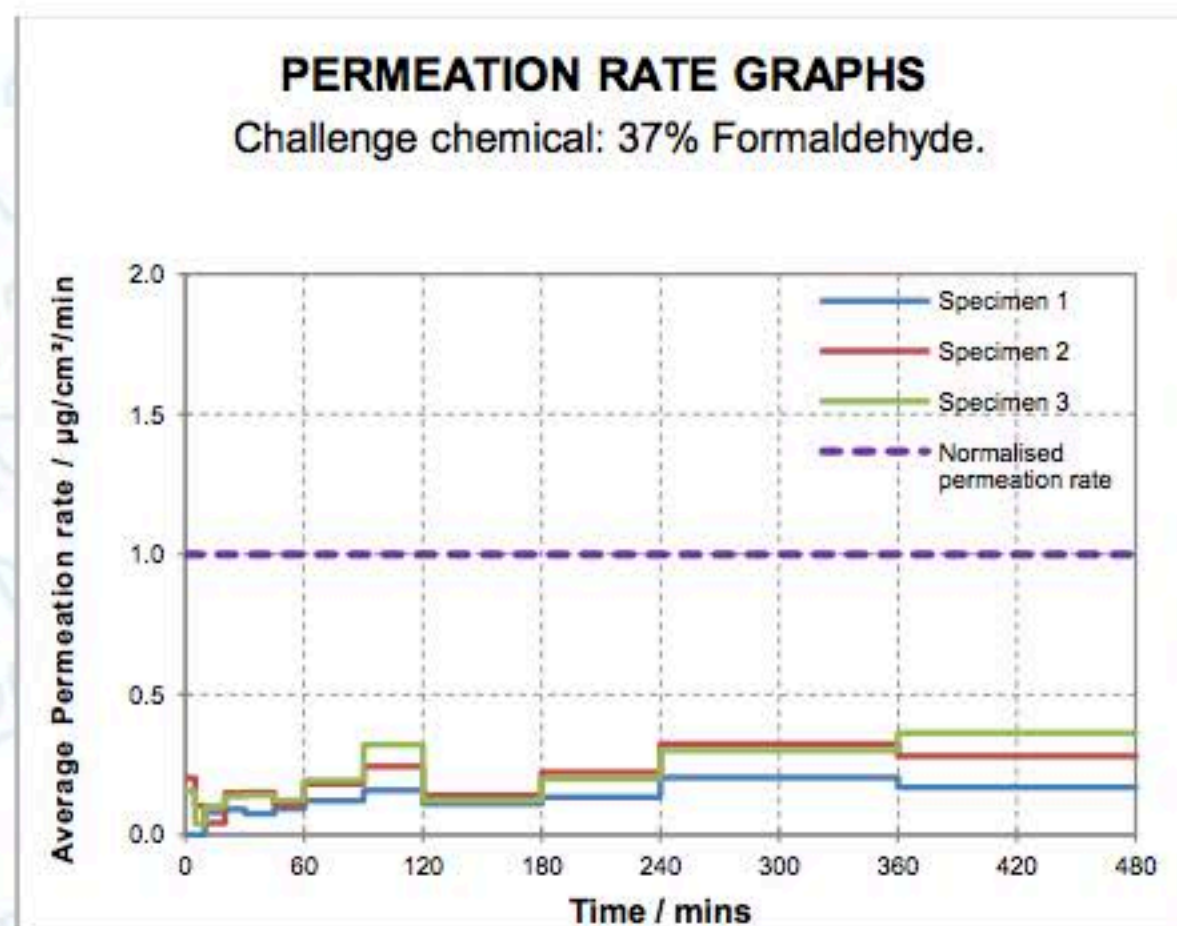


Test/Property	Sample reference:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical:	30% Hydrogen peroxide	
		Normalised permeation rate (NPR): 1 µg/cm ² /min		
		Detection technique:	Electrochemical detector (periodic measurement)	
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm) [△]	Breakthrough time (mins) [▽]	
	1 (Blue)	0.09	>480	
	2 (Green)	0.08	>480	
	3 (Black)	0.08	>480	
		Test result:	>480	
		UoM:	< 1	
Visual appearance of specimens after testing:		No change		



Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

Test/Property	Sample reference:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 37% Formaldehyde		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: 45 – 65 ml/min (each cell constant to within ± 10%)		
		Test temperature: (23 ± 1) °C		
	Specimen	Thickness (mm)△	Breakthrough time (mins)▼	
	1 (Blue)	0.10	>480	
	2 (Green)	0.08	>480	
	3 (Black)	0.07	>480	
	Test result:	>480		
	UoM:	< 1		
Visual appearance of specimens after testing:		No change		



Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

- △ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.
- ▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing.
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are not 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

10. PROVISION OF SERVICES

- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.

- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.

- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.

- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.

- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.

- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.

- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.

- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.

- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.

- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.

- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

12. DELIVERY AND NON-DELIVERY OF GOODS

- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.

- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.

- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.

- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.

- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.

- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13. RISK/TITLE OF GOODS

- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.

- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:

- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.

- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -

- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.

- 13.4 Until ownership of Goods has passed to the Client, the Client shall:

- a) hold the Goods as SATRA's bailee;
b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.

- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.

- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:

- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.

- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.

- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14. PATENTS

- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15. WARRANTY OF GOODS

- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16. DEFECTIVE GOODS

- 16.1 Subject to clauses 16.6 and 16.7 if:

- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
b) SATRA is given a reasonable opportunity of examining such Goods; and
c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.

- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.

- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.

- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.

- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.

- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:

- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;

- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:

- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.

- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

Customer details: SATRA Technology Services (Dongguan) Ltd SATRA reference: CHM0298451/2022/LH
Unit 110, Xinzhongyin Garden /B
Hongwei Road Your reference: CHT0298236
Xiping, Nancheng District
DONGGUAN CITY
Guangdong Province
China
523079
Date of report: 17th June 2020
Samples received: 26th May 2020
Date(s) work carried out: 4th to 10th June 2020

TECHNICAL REPORT

SATRA Technology Services (Dongguan) Ltd:

Customer: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei 052260
China

Subject: EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals on gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black).

Conditions of Issue:

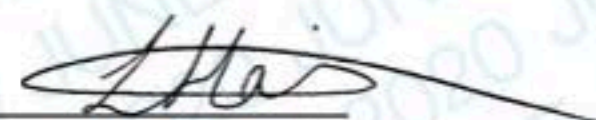
This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Lorna Harding
Position: Technologist
Department: Chemical & Analytical Technology



WORK REQUESTED:

Samples of gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black) were received on the 26th May 2020 for testing in accordance with EN ISO 374-4:2019.

SAMPLE SUBMITTED:



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue)



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Green)



Samples described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Black)

CONCLUSION:

When assessed in accordance with EN ISO 374-4:2019 the samples of gloves described as Disposable Vinyl/Nitrile Blend Examination gloves, Powder free (Blue/Green/Black) achieved the following degradation results:

Chemical	Mean degradation / %
30% Hydrogen peroxide (CAS: 7722-84-1)	2.7
37% Formaldehyde (CAS: 50-00-0)	-8.1
40% Sodium hydroxide (CAS: 1310-73-2)	-1.2

TESTING REQUIRED:

- EN ISO 374-4:2019. Protective gloves against dangerous chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

RESULTS:

Sample description:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1 (Black)	Glove 2 (Green)	Glove 3 (Blue)
	10.9	0.6	-3.3
Mean degradation (DR) / %:	2.7		
Standard deviation (σ_{DR}) / %:	7.3		
UoM / ± %:	20.1		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1 (Black)	Glove 2 (Green)	Glove 3 (Blue)
	-7.7	-15.2	-1.4
Mean degradation (DR) / %:	-8.1		
Standard deviation (σ_{DR}) / %:	6.9		
UoM / ± %:	19.5		
Appearance of samples after testing:	No change		

Sample description:	Disposable Vinyl/Nitrile Blend Examination gloves, Powder free		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1 (Black)	Glove 2 (Green)	Glove 3 (Blue)
	5.6	-4.8	-4.5
Mean degradation (DR) / %:	-1.2		
Standard deviation (σ_{DR}) / %:	5.9		
UoM / ± %:	19.9		
Appearance of samples after testing:	No change		

NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing.
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstich, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- a) In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- b) In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- a) SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- b) the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- a) hold the Goods as SATRA's bailee;
- b) store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- c) not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- b) SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- c) if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- a) the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- b) SATRA is given a reasonable opportunity of examining such Goods; and
- c) the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- a) the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- b) the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- c) the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- d) the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- a) SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- b) nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – September 2019

Customer details: Shijiazhuang Hongray Group Co., Ltd
South Tongda Road, East District
Jinzhou City
Hebei
China
052260

SATRA reference: CHT0298236 /2021

Your reference: -

Date of report: 4 July 2020

Samples received: 20 May 2020

Date(s) work carried out: 15 June 2020

TECHNICAL REPORT

Subject:

EN ISO 21420: 2020 size, dexterity and Innocuousness test & EN 374-2: 2014 air leak and water leak test on Disposable Vinyl/Nitrile Blend Examination Gloves, Colour: blue/green/black, Powder free, Size: XS (6)-XL (10).

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides a coverage probability of approximately 95%.

Report signed by: Adam Zhang
Position: Technologist
Department: China Testing

WORK REQUESTED

Samples described as Disposable Vinyl/Nitrile Blend Examination Gloves, Colour: blue/green/black, Powder free, Size: XS (6)-XL (10) were received by SATRA on 20 May 2020 for testing in accordance with EN ISO 21420: 2020 and EN 374-2: 2014.

SAMPLE SUBMITTED

Samples described as Disposable Vinyl/Nitrile Blend Examination Gloves, Colour: blue/green/black, Powder free, Size: XS (6)-XL (10)

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves

EN ISO 21420: 2020 Clause 5.2 – Dexterity

EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves

EN 374-2: 2014 Clause 7.2 – Air leak

EN 374-2: 2014 Clause 7.3 – Water leak

CONCLUSION

The samples described as Disposable Vinyl/Nitrile Blend Examination Gloves, Colour: blue/green/black, Powder free, Size: XS (6)-XL (10) were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table

EN ISO 21420: 2020 Clause 5.2 – Level 5

EN ISO 21420: 2020 Clause 4.2* – Pass PAHs, phthalates, DMFa and pH value

EN 374-2: 2014 Clause 7.2* – Pass

EN 374-2: 2014 Clause 7.3* – Pass

All tests marked * in this technical report were subcontracted to a chemical test facility accredited to ISO/IEC 17025: 2005 by CNAS.

Detailed results are included on the following page(s)

Testing

Testing was carried out in accordance with EN ISO 21420: 2020

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Test Results

Table 2 – EN ISO 21420: 2020 Test Results.

Clause / Test	Requirement	Test Results			UoM (See note ♣)	Result	
5.1 Glove length, comfort and fit	N/A	Length /mm			± 1.10 mm	N/A	
		Size	1	2			3
		6	227	226			226
		Comfortable on fit					
		7	237	242			243
		Comfortable on fit					
		8	248	251			254
		Comfortable on fit					
		9	259	260			260
		Comfortable on fit					
10	266	267	265				
Comfortable on fit							
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm			N/A	Level 5
		6	5.0				
		7	5.0				
		8	5.0				
		9	5.0				

Additional Information / Notes

Note ♣ – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

Innocuousness Testing

RESULTS:

Sample Item	Sample Description	Location	Style
I001	Blue soft plastic	Gloves	1
I002	Green soft plastic	Gloves	2
I003	Black soft plastic	Gloves	3

pH Value-EN 420:2003+A1:2009

Test Method I : With reference to ISO 4045:2008, Analyzed by pH meter.

Test Method II: With reference to ISO 3071:2005, Analyzed by pH meter.

Requirement:	3.5-9.5
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-	Unit	Result		
Test Item(s)	-	I001	I002	I003
Test Method	-	II	II	II
Parameter	-	-	-	-
pH Value of Extracting Solution	-	5.33	5.33	5.33
Temp. of Aqueous Extract	deg. C	25.0	25.0	25.0
pH Value of Aqueous Extract	-	6.0	6.0	6.0
Difference Figure	-	-	-	-
Conclusion	-	PASS	PASS	PASS

Note / Key : deg. C = degree Celsius (°C) Temp. = Temperature

Remark: Result(s) was (were) reported the average value from two trials.
Tested part(s) was/were specified by client.

RESULTS:

Polycyclic Aromatic Hydrocarbons (PAHs) Content –European Parliament and Council Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII with its Latest Amendment , Entry 50, point 5

Test Method : With reference to test method mentioned in German AfPS GS 2014:01 PAK.

Maximum Allowable Limit:	Each of all listed PAHs: 1.0 mg/kg ^[a]
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Tested Item(s)	Result			Conclusion
	Detected Analyte(s)	Conc.	Unit	
I001+I002+I003	ND	ND	mg/kg	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit (mg/kg) : Each : 0.2;
mg/kg = milligram per kilogram = ppm = part per million

Remark: The list of polycyclic aromatic hydrocarbons is summarized in table of Appendix.
[a]denotes as this maximum allowable limit applies to product(s) placed on the market for the first time on or after December 27, 2015 only.
Rubber or plastic component(s) of articles that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity under normal or reasonably foreseeable conditions of use is (are) applicable to be tested. Such articles include amongst others:
— sport equipment such as bicycles, golf clubs, racquets
— household utensils, trolleys, walking frames
— tools for domestic use
— clothing, footwear, gloves and sportswear
— watch-straps, wrist-bands, masks, head-bands
Tested part(s) was/were specified by client.
Composite testing(s) was/were specified by client.

APPENDIX					
List of Polynuclear Aromatic Hydrocarbons:					
No.	Name of Analytes	CAS-No.	No.	Name of Analytes	CAS-No.
1	Chrysene	218-01-9	5	Dibenzo (a,h) anthracene	53-70-3
2	Benzo (a) pyrene	50-32-8	6	Benzo (b) fluoranthene	205-99-2
3	Benzo (e) pyrene	192-97-2	7	Benzo (j) fluoranthene	205-82-3
4	Benzo (a) anthracene	56-55-3	8	Benzo (k) fluoranthene	207-08-9

RESULTS:

Phthalates Content in Toys and Childcare Articles - European Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) with Amendments up to EU No. 412/2012, Annex XVII, Entry 51

Test Method : with reference to ISO 14389:2014, then analyzed by GasChromatographMass Spectrometer.

Analyte	Requirement (%,w/w)	Result(%,w/w)
		Test Item(s)
		I001+I002+I003
Di-(2-ethylhexyl) phthalate (DEHP)	-	ND
Dibutyl phthalate (DBP)	-	ND
Benzylbutyl phthalate (BBP)	-	ND
Diisobutyl phthalate (DIBP)	-	ND
Sum of DEHP+DBP+BBP+DIBP	0.1	ND
Conclusion	-	PASS

Note / Key : ND = Not detected(<Detection Limit) Detection Limit : 0.005%

mg/kg = milligram per kilogram = ppm = part per million

10 000 mg/kg = 1 % % = percent

Remark: Composite testing(s) was/were specified by client.

Dimethylformamide(DMFA) Content—With reference to Substance of Very High Concern for authorization published by European Chemicals Agency (ECHA) Regarding Regulation (EC) No. 1907/2006 concerning REACH

Test Method : With reference to ISO/TS 16189:2013, and then analyzed by Gas Chromatograph Mass Spectrometer.

Analyte	Unit	Result	Client's Requirement
		Test Item(s)	
		I001+I002+I003	
Dimethylformamide(DMFA)	mg/kg	ND	1000
Conclusion	-	PASS	-

Note / Key : ND = Not detected (<Detection Limit) Detection Limit (mg/kg) : 5

mg/kg = milligram per kilogram = ppm = part per million

Remark: Composite testing(s) was/were specified by client.

Testing

Testing was carried out in accordance with EN 374-2: 2014

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at $(23 \pm 2)^{\circ}\text{C}$ and $(50 \pm 5)\%$ relative humidity.

Requirements

Requirements for EN 374-2: 2014

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

Test Results

EN 374-2: 2014 Test Results

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total air pressure used	3.0 kPa	NA	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
7.3 Water leak test	10	No leaks detected		
	Sample size	Leaks	NA	Pass
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

*** End of Report ***

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are, to the maximum extent permitted by law, hereby excluded.
- 1.2 SATRA Technology Services (Dongguan) Limited (东莞赛卓检测技术服务有限公司), its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for, or supply Goods to, persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to any Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealings.
- 1.4 Unless otherwise agreed in writing, no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - 1.5.1 "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - 1.5.2 "Services" are the work or services to be supplied or performed under the Contract (including, where relevant the supply of software, components and consumables); and
 - 1.5.3 "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment); and
 - 1.5.4 "PRC" means the People's Republic of China.
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the Goods or Services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try to provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services, the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors.
- 3.6 With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstich, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.7 SATRA shall observe all statutory provisions with regard to data protection. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.

- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - 5.2.1 death or personal injury caused by its negligence or the negligence of its employees or agents;
 - 5.2.2 fraud or fraudulent misrepresentation; or
 - 5.2.3 any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or RMB500,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these terms and conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 To the extent permitted by applicable laws and regulations, all provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms and conditions and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to a Contract shall be effective unless it is in writing, expressly stated to amend the Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, the terms of clause 9.3 shall apply.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, refer the dispute to the Shenzhen Court of International Arbitration for arbitration in accordance with its rules of arbitration then in force. The place of arbitration shall be Shenzhen. The number of arbitrators shall be one. Unless agreed otherwise, the language used for the arbitration shall be English and Chinese and each Party shall have the right to have its own interpreters and legal advisors present throughout the arbitration. The arbitral award shall be final and binding upon the Parties and the Parties agree to be bound thereby and to act accordingly. Application may be made to any court having jurisdiction for judicial acceptance of the award and an order of enforcement and execution.
- 9.4 Unless specified otherwise in a Contract, the laws of the PRC shall govern the interpretation of a Contract.

10. PROVISION OF SERVICES

- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Client's specific instructions and as confirmed by SATRA as part of the Contract review process.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client.
- Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.

11 CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES

- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12 DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to take delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).

13 RISK/TITLE OF GOODS

- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- 13.2.1 In the case of sales where delivery of Goods is made in the PRC, SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
- 13.2.2 In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- 13.3.1 SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
- 13.3.2 the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:

- 13.4.1 hold the Goods as SATRA's bailee;
- 13.4.2 store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
- 13.4.3 not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- 13.4.4 maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- 13.6.1 the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
- 13.6.2 SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
- 13.6.3 if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of a Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.

14 PATENTS

- 14.1 SATRA gives no indemnity against any claim of infringement of any Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of a Patent, Registered Design, Trade Mark or Copyright published at the date of a Contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.

15 WARRANTY OF GOODS

- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.

16 DEFECTIVE GOODS

- 16.1 Subject to clauses 16.6 and 16.7 if:
- 16.1.1 the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
- 16.1.2 SATRA is given a reasonable opportunity of examining such Goods; and
- 16.1.3 the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business,
- then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- 16.6.1 the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
- 16.6.2 the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
- 16.6.3 the Client has breached any of the terms of the Contract under which the Goods were supplied; or
- 16.6.4 the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- 16.7.1 SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
- 16.7.2 nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – May 2017

Auditee :	Ever Light Plastic Products Co., Ltd.
Audit Date From :	15/10/2020
Audit Date To :	16/10/2020
Expiry Date of the Audit :	Please refer to the producer profile in the amfori BSCI platform
Auditing Company :	BureauVeritas
Auditor's Name(s) :	Ferric He(Lead), Vera Wang
Auditing Branch (if applicable) :	



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Rating Definitions



Rating	A combination of ratings per Performance Area where:	Consequence																																							
A Very Good	<ul style="list-style-type: none">• Minimum 7 Performance Areas rated A• No Performance Areas rated C, D or E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr></table>	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	B	A	A	A	A	A	A	A	B	B	B	B	B	B	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	A	A	A	A	A	A	A																													
A	A	A	A	A	A	A	A	A	A	B	B	B																													
A	A	A	A	A	A	A	B	B	B	B	B	B																													
B Good	<ul style="list-style-type: none">• Maximum 3 Performance Areas rated C• No Performance Areas rated D or E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td></tr><tr><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td></tr></table>	A	A	A	A	A	A	B	B	B	B	B	B	B	A	A	A	A	A	B	B	B	B	B	B	B	C	B	B	B	B	B	B	B	B	B	B	C	C	C	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	B	B	B	B	B	B	B																													
A	A	A	A	A	B	B	B	B	B	B	B	C																													
B	B	B	B	B	B	B	B	B	B	C	C	C																													
C Acceptable	<ul style="list-style-type: none">• Maximum 2 Performance Areas rated D• No Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>C</td><td>C</td><td>C</td><td>C</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td></tr><tr><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td></tr></table>	A	A	A	A	A	A	A	A	A	C	C	C	C	A	A	A	A	A	B	B	B	B	C	C	C	D	C	C	C	C	C	C	C	C	C	C	C	D	D	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	C	C	C	C																													
A	A	A	A	A	B	B	B	B	C	C	C	D																													
C	C	C	C	C	C	C	C	C	C	C	D	D																													
D Insufficient	<ul style="list-style-type: none">• Maximum 6 Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>D</td><td>D</td><td>D</td></tr><tr><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td><td>D</td><td>E</td></tr><tr><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	A	A	A	A	D	D	D	A	A	A	B	B	B	C	C	C	D	D	D	E	D	D	D	D	D	D	D	D	E	E	E	E	E	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	A	D	D	D																													
A	A	A	B	B	B	C	C	C	D	D	D	E																													
D	D	D	D	D	D	D	D	E	E	E	E	E																													
E Unacceptable	<ul style="list-style-type: none">• Minimum 7 Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>A</td><td>A</td><td>B</td><td>B</td><td>C</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	E	E	E	E	E	E	E	A	A	B	B	C	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	amfori BSCI Participants shall closely oversee the auditee's progress as the producer may represent a higher risk than other business partners.
A	A	A	A	A	A	E	E	E	E	E	E	E																													
A	A	B	B	C	D	E	E	E	E	E	E	E																													
E	E	E	E	E	E	E	E	E	E	E	E	E																													
Zero Tolerance	A Zero Tolerance Issue was identified (see amfori BSCI System Manual Part V – Annex 5: amfori BSCI Zero Tolerance Protocol)	Immediate actions are required. The amfori BSCI Zero Tolerance Protocol is to be followed.																																							

Main Auditee Information

Name of producer :	Ever Light Plastic Products Co., Ltd.		
DBID number :	404417		
Audit ID :	195058		
Address :	Donggao Industrial Zone, Zanhuan Shijiazhuang		
Province :	Hebei	Country :	China
Management Representative :	Min Ren		
Contact person:	Min Ren	Sector :	Non-Food
Industry Type :	Plastic Industry	Product group :	Plastic and articles thereof
Product Type :	PVC gloves		

Audit Details


Audit Range :	<input checked="" type="checkbox"/> Full Audit	<input type="checkbox"/> Follow-up Audit
Audit Scope :	<input checked="" type="checkbox"/> Main Auditee	<input type="checkbox"/> Main Auditee & Farms
Audit Environment :	<input checked="" type="checkbox"/> Industrial	<input type="checkbox"/> Agricultural <input type="checkbox"/> Small Producer
Audit Announcement :	<input checked="" type="checkbox"/> Fully-Announced	<input type="checkbox"/> Fully-Unannounced <input type="checkbox"/> Semi-Announced
Random Unannounced Check (RUC) :	No	
Audit extent (if applicable) :	none	
Audit interferences or contingencies (if applicable) :	none	
Overall rating :	C	
Need of follow-up :	Yes	If YES, by : 16/10/2021

Rating per Performance Area (PA)

PA 1	PA 2	PA 3	PA 4	PA 5	PA 6	PA 7	PA 8	PA 9	PA 10	PA 11	PA 12	PA 13
B	B	A	A	B	D	A	A	A	A	A	A	A

Executive summary of audit report

Factory name: Ever Light Plastic Products Co., Ltd. 石家庄鸿锐集团鸿迪塑胶制品有限公司
 Factory address: Donggao Industrial Zone, Zanhuan, Hebei Province, China.
 中国河北省赞皇县东高工业区
 Business license number: 91130100784064765D

The factory was established on January 18, 2006, it was mainly manufacturing PVC gloves. The main production activities in the factory were mixing, molding, testing, inspection and packing.
 Per factory management interview, there was no peak season in the factory. Their capacity was 80,000 boxes per month.
 The audited factory owned one 1-storey production building (partial area was 2-storey), one 1-storey canteen and one 3-storey dormitory building. No transportation was provided for workers.
 There were totally 163 employees in the factory, including 34 non-production employees and 129 production employees. There were 46 male employees and 117 female employees. The youngest employee worked in the factory was 26 years old.
 Production workers' working hours were recorded by IC card system with detailed time in and time out information. There was only three shifts for production employees, the 1st shift was from 08:00 to 16:00, the 2nd shift was from 16:00 to 24:00 and the 3rd shift was from 00:00 to 08:00; there was one shift for office workers, it was from 08:00 to 12:00 and 13:30 to 17:30, no overtime work arranged in weekdays. Production workers were paid in daily rate at the 25th day of next month by cash.

According to the payroll and attendance records of 16 sample employees from Nov 2019, 16 sample employees from Feb 2020 and 16 sample employees from Aug 2020, it was noted that the regular wage of all sampled employees in these months was minimum RMB 90 per day, the local minimum wage was RMB 1680 per month equivalent to RMB 77/day since Nov 1, 2019 and the local minimum RMB 1480/month and equivalent to RMB 68/day before Nov 1, 2019. All sampled employees were paid with 200% of regular wages for their work on rest days, which was in line with statutory requirement. No overtime works were noted in weekdays and statutory holidays. Additional 5 records were sampled in Sep 2020 for working hour verification. The sampled records indicated that employees' maximum overtime hours was 0 hours a weekday, 8 hours a rest day, 0 hour a holiday, 8 hours a week and 40 hours a month in the testing months. The maximum weekly working hours were 48 hours. The longest consecutive working days were 6 days in the testing periods.

According to the social insurance payment receipt of Sep 2020 provided by factory management, it was noted that only 46 out of 163 employees (28.22%) were provided with pension, unemployment, maternity and medical insurance, all 163 workers were provided with accident insurance, but not all workers were provided with all kinds of social insurance.

The attendance records were cross-checked against production records, attendance records, payroll records and confidential interviews, no inconsistencies regarding working hours were found.
 At the end of the audit, a closing meeting was held with the factory representatives. All of the findings were disclosed and discussed and a corrective action plan was explained to the factory representatives, Mrs. Min Ren/QA supervisor agreed with the findings and signed the corrective action plan.

Opening meeting factory representatives (name and titles)
 Mrs. Caihui Wang/HR staff;
 Mr. Lijie Tian/Sales supervisor;
 Mrs. Lili Zhang/Quality supervisor;
 Mr. Nan Zou/Health and safety supervisor;
 Mrs. Yuli Wu/Manager;
 Mr. Dongbo Qi/Worker representative;
 Mrs. Min Ren/QA supervisor;

Remark:

- There was no contractor used by the auditee, which makes the contractor license/permit not applicable.
- There was no agency used by the auditee, which makes the agency labor contract not applicable.
- The Government waivers were not applicable in the auditee.
- The Collective bargaining agreements were not applicable in the auditee.

5. Audit Company: Bureau Veritas Consumer Products Service
Audit Company APSCA Number: 11600002
Lead Auditor Name: Ferric He
APSCA Auditor Registered Number: RA 21702093
Member Auditor Name: Vera Wang
APSCA Auditor Registered Number: RA 21700004

Ratings Summary


Auditee's background information			
Auditee's name :	Ever Light Plastic Products Co., Ltd.	Legal status :	Limited company
Local Name :	石家庄鸿锐集团鸿迪塑胶制品有限公司 (91130100784064765D)	Year in which the auditee was founded :	2006
Address :	Donggao Industrial Zone, Zanhuan	Contact person (please select) :	Min Ren
Province :	Hebei	Contact's Email :	renmin@hongray.com.cn
City :	Shijiazhuang	Auditee's official language(s) for written communications :	Chinese
Region :	North East Asia	Other relevant languages for the auditee :	None
Country :	China	Website of auditee (if applicable) :	None
GPS coordinates :	N37°42'20" E114°30'9"	Total turnover (in Euros) :	12671059.00
Sector :	Non-Food	Of which exports % :	80.00
Industry :	Plastic Industry	Of which domestic market % :	20.00
If other, please specify :		Production volume :	80,000 boxes per month
Product Group :	Plastic and articles thereof	Production cost calculation :	Yes
If other, please specify :		Lost time injury calculation cost :	Yes
Product Type :	PVC gloves		

Auditee's employment structure at the time of the audit		
Total number of workers :	163	Total number of workers in the production unit to be monitored (if applicable) :
		0
	MALE WORKERS	FEMALE WORKERS
Permanent workers	46	117
Temporary workers	0	0
In management positions	0	1
Apprentices	0	0
On probation	0	0
With disabilities	0	0
Migrants (national citizens)	0	0
Migrants (foreign citizens)	0	0
Workers on the permanent payroll	46	117
Production based workers	0	0
With shifts at night	20	109
Unionised	0	0
Pregnant	-	0
On maternity leave	-	0

Finding Report



Performance Area 1 : Social Management System and Cascade Effect

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B

Deadline date: 16/12/2020

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory established complete policy and procedure on social accountability. For example, the procedures on hiring, discrimination, forced labor, freedom of association, payment and benefit, working hours, dealing with grievances, training workers, promoting ethical behavior were established by the factory. The factory also established policy to manage its own significant business partners, supplier's social performance were monitored when they select suppliers. However, there were gaps had been identified in this performance area.

工厂建立了完整的社会责任政策和程序，例如程序中包括招聘、歧视、强迫劳动、自由结社、工资报酬、工作时间、申诉系统、员工培训、反腐败等内容。工厂还创建了供应商的筛选程序，程序显示工厂在选择供应商时，会评估到其社会责任表现。但是，基于令人满意的证据，主要受审核方没有完全尊重这个原则。

- 1.4 -** The factory had established the production capacity assessment procedure, but they had not assessed production capacity, workers' overtime working hours exceeded local law's requirement. This violated Performance Area 1: Social Management System and Cascade Effect 1.4

工厂已建立生产能力评估程序，但还未进行生产能力评估，导致员工的加班时间超过法规要求。根据执行领域1：社会管理体系和级联效应 1.4

Remarks from Auditee:

The factory management agreed the finding and no other comment.

Performance Area 2 : Workers Involvement and Protection

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B

Deadline date: 16/12/2020

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory established policy and provided training for workers to let them knew their personal rights. The grievance procedure was established, workers could communicate with worker representatives, and raise grievance through suggestion box. And the related policy had been posted in workshop to make workers aware of their rights and responsibilities. However, there were gaps had been identified in this performance area, workers did not completely knew BSCI COC content, the grievance procedure did not involve with its stakeholders.

工厂建立了制度并推行培训，以便让员工了解自身的权利。工厂建立了申诉机制，可以和员工代表沟通，或者通过意见箱反馈意见。并且已经通过在生产车间对相关政策进行公示，以便于让员工更好地了解这一政策。但是被审核方在该绩效区域有差距，员工并不完全了解BSCI COC内容，申诉程序没有涉及到利益相关方。

- 2.4 -** The factory had provided the social responsibility requirement and BSCI COC training for workers, however, the workers did not completely know the requirements of Amfori BSCI Codes per employee interview. This violated Performance Area 2: Workers Involvement and Protection 2.4.

工厂有给员工提供了社会责任要求和BSCI COC 培训，但是根据员工访谈员工并不完全了解Amfori BSCI守则的要求。根据执行领域2：工人参与和保护2.4

- 2.5 -** The established grievance mechanism did not include all interested parties, it was only applicable for internal part. In accordance with Performance Area 2: Workers Involvement and Protection 2.5.

工厂建立的申诉机制没有包含所有利益相关方，只是对工厂内部适用。根据执行领域2：工人参与和保护2.5

Remarks from Auditee:

The factory management agreed the finding and no other comment.

Performance Area 3 : The rights of Freedom of Association and Collective Bargaining

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory had established policy on the rights of freedom of association and collective bargain per BSCI COC requirements, worker representatives were elected freely, suggestion box was provided. Besides, the auditee has provided trainings to all workers regarding freedom of association and collective bargain. Workers could communicate with the worker representatives without interruption. All employees were not discriminated whether they were worker representatives or not.

工厂依据BSCI的行为准则建立了自由结社方面和集体谈判权的方针政策和程序文件，有自由选举员工代表，并设置了意见箱。此外工厂为所有员工提供了这方面的培训。员工可以不受干扰的和员工代表进行交流。此外所有员工无论他们是否是员工代表都不会受到歧视。

Remarks from Auditee:

None

Performance Area 4 : No Discrimination	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>The factory had established procedure and policy on non-discrimination per BSCI COC requirement, trainings regarding anti-discrimination were provided. All interviewed workers indicated that no discrimination case in the factory, no discriminate pregnancy testing was conducted for workers, and all employees were equal regardless of their race, age, gender and skin for overtime work, training and wage raising.</p> <p>工厂依据BSCI的行为准则建立了非歧视方面方针政策和程序文件，培训会涉及非歧视政策。员工访谈没有汇报歧视方面问题，工厂也没有要求员工验孕，所有员工不管什么种族，年龄，性别，肤色都一律平等享有加班机会、培训机会和加薪机会。</p>	
Remarks from Auditee: None	
Performance Area 5 : Fair Remuneration	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: B	Deadline date:16/01/2021
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>The factory had established rule to ensure that all employees would be paid with enough wages per legal requirement. Based on document review, management interview and workers interview, the factory had provided the benefits such as paid annual leave, paid statutory holidays and etc for employees. Worker's wage was calculated in daily rate, they were paid with at least RMB 90 per day, which was higher than local minimum wage standard; the wage was paid at the 25th day of the next month by cash, the slip was provided; wages were paid in time. However, the factory did not ensure all workers were provided with all kinds of social insurance.</p> <p>工厂已经通过厂规来确保员工能依法获得足够的工资。根据文件审核，员工访谈及管理层访谈，被审核方已经依法为员工提供了带薪年假，带薪年假定假日等。员工工资为日薪工资，最低的日工资为RMB 90/天，高于当地最低工资水平；工厂会在每月25日通过现金支付员工上个月的工资，并且为员工提供工资条；没有发生拖欠工资的情况。但工厂没有确保所有员工获得所有类型的社保。</p> <p>5.5 - According to the social insurance payment receipt of Sep 2020 provided by factory management, it was noted that only 46 out of 163 employees (28.22%) were provided with pension, unemployment, maternity and medical insurance, all 163 workers were provided with accident insurance, but not all workers were provided with all kinds of social insurance. Workers indicated that they were voluntary to participate in social insurance. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Article 73 of the Labor Law of the People's Republic of China.</p> <p>根据厂方提供的2020年9月的社会保险缴费单据显示，工厂为46/163名员工(28.22%)提供了养老,生育,失业,医疗保险，为所有员工提供了工伤保险，但没有达到全员参保。员工表示是自愿参加社保的，工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第73条</p>	
Remarks from Auditee: The factory management agreed the finding and no other comment.	
Performance Area 6 : Decent Working Hours	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: D	Deadline date:16/01/2021
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>The factory had established working hour policy, their regular working hours were 5 days per week and 8 hours per day. There were three working shifts for production workers, it was from 08:00-16:00, 16:00-24:00 and 24:00-08:00. The factory used IC card attendance system to record workers' attendance status. According to the sampled attendance records, employees did not work overtime in weekdays, the overtime hours were 8 hours per week, the maximum overtime hours were 40 hours per month. The maximum total working hours per week were 48 hours per week. The longest consecutive days worked were 6 days and had at least one day rest after 6 days. Workers were voluntary to participate in overtime work.</p> <p>工厂建立了工时管理制度，工厂的正班工时是每周5天，每天8小时。生产员工按照三个班次安排，分别为08:00-16:00, 16:00-24:00, 24:00-08:00。工厂采用IC卡考勤来记录员工的考勤状态。抽样的考勤里面，员工平时没有加班，每周加班8小时，每月加班最多40小时。每周的总工作时间最多是48小时。最多连续工作6天之后有至少一天休息。员工加班均为自愿参加。</p> <p>6.2 - According to the payroll and attendance records of 16 sample employees from Nov 2019, 16 sample employees from Feb 2020, 16 sample employees from recent paid month Aug 2020 and 5 records from unpaid full month of Sep 2020, it was noted that 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Nov 2019, which was not in compliance with the legal requirement; 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Feb 2020, which was not in compliance with the legal requirement; 16 out of 16 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Aug 2020, which was not in compliance with the legal requirement; All employees interviewed represented that they were voluntarily to work overtime and the production workload was acceptable. Factory management agreed with the issue and would take corrective action as soon as possible. This Violated Article 41 of the Labor Law of the PRC.</p> <p>根据工厂提供的工资考勤记录，抽样2019年11月16名员工，2020年2月16名员工，发薪月份2020年8月16名员工和未发薪月份2020年9月5名员工，显示16/16名员工在2019年11月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；16/16名员工在2020年2月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；16/16名员工在2020年8月的加班时间为40小时，超过每月加班时间不能超过36小时的法律规定；访谈员工表示自愿加班，工作强度也可以接受。工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第41条</p>	
Remarks from Auditee: The factory management agreed the finding and no other comment.	

Performance Area 7 : Occupational Health and Safety

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date: 16/12/2020

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The committee of health and safety was set up by the factory, and EHS supervisor was responsible for the affairs of health and safety. Factory had conducted internal assessment for the risk of workshop accordingly to reduce potential health and safety risks. For fire safety, the factory equipped extinguishers in every workshop. Fire alarms, emergency lights and fire hydrant were available in the factory. All these Fire facilities were checked per month, fire drill for day shift and night shift was conducted. For mechanism safety, all operation instructions were set up; workers were well trained to operate it correctly. The factory also set up emergency procedure and trained sufficient first aiders for providing the service of first aid. The first aid box was also available in every workshop. The factory asked third party to conduct occupational health impact factors testing for workshops, workers were provided with free occupational health examination. Clean potable water was also provided, it was free for access.

工厂创建了员工的健康安全委员会，由EHS代表负责整体的健康与安全。工厂按照车间情况对工厂内部进行健康安全风险评估，消除潜在的安全风险。在消防安全方面，工厂给所有车间配备了灭火器，消防栓，应急灯、消防警铃。消防设施每月都会进行检查，有针对白班和夜班进行消防演习。在机械安全方面，工厂制定了相应的操作规程，并且给员工提供了操作培训。在急救政策方面，工厂制定了急救政策，工厂给每个车间配备了药箱，而且工厂有充足数量的急救员。工厂委托了第三方机构对车间职业危害因素进行了监测，并为员工提供了免费的职业健康体检。同时，工厂也提供了饮用水给员工，员工可随时喝水。

7.3 - It was noted that the health and safety risk assessment for workshops was conducted insufficiently. The risk assessment did not include the chemical safety risk in mixing workshop, such as the newly updated MSDS should be provided there. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Performance Area 7: Occupational Health and Safety 7.3.

工厂为车间进行的健康安全风险评估不充分。风险评估没有包含配料车间使用的化学品的风险，比如应该提供最新的MSDS等。根据执行领域7：职业健康和安全 7.3. 工厂同意该问题并表示尽快改善。

7.7 - It was noted that there was no newly updated version MSDS onsite for hazardous chemical additive in mixing workshop. In accordance with Article 27 of the Regulation For Chemical Usage Safety in Work Place:

现场发现，配料车间没有张贴危险化学品添加剂的最新版本的MSDS。根据《工作场所安全使用化学品规定》第27条：

7.23 - No transportation was provided for workers, it was not applicable.

工厂没有为员工提供交通，不适用。

Remarks from Auditee:

The factory management agreed the finding and no other comment.

Performance Area 8 : No Child Labour

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory had established procedures on no child labor, and remediation procedures are available in case child labor was found, the requirements were trained to all workers. Age verification mechanism was used upon recruitment to ensure all workers were over 16 years old, it was in line with local law requirement. Currently, no child labor was detected or reported.

工厂建立了不使用童工和童工补救措施程序文件，并将相关要求培训告知员工。招聘过程中工厂有年龄识别体系确保员工都满16岁，符合法规要求。审核过程没有发现童工或者汇报童工。

Remarks from Auditee:

None

Performance Area 9 : Special protection for young workers

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory established policy to indicate that young worker would be protected properly, such as young worker would not be arranged in unreasonable position, regular health examination would be provided. The requirements were also trained to workers. According to document review, onsite observation and workers interview, no young worker was used in the factory currently.

工厂建立了政策，表明会合理保护未成年工人，比如不安排不合理的岗位，定期提供体检等。工厂有将相关要求培训告知员工。文件核实、现场观察、员工访谈确认，工厂目前没有使用到未成年工人。

Remarks from Auditee:

None

Performance Area 10 : No Precarious Employment	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>Labor contracts were signed between the factory and each worker, the contracts statement included the description of working hours, training, rest time and leave, payment and payment method, which were in accordance with legal requirement and ILO. The factory had communicated all labor contract contents to all workers before they entered the factory. Meanwhile, the factory provided a copy of contract to every worker. No illegal worker was used in the factory, all of them were employed by the factory directly.</p> <p>工厂和每个员工均签订了劳动合同，劳动合同的内容包括工时，培训，休息时间和假期，报酬和支付条件，这些内容均符合法规以及国际标准。工厂有在员工入职前有告知员工合同的内容。同时工厂提供了一份劳动合同副本给员工。工厂无不合法用工形式存在，所有员工均为工厂自己招聘。</p>	
Remarks from Auditee: None	
Performance Area 11 : No Bonded Labour	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>The factory had established procedures on non-bond labor and all employees were freely to terminate their relationship with the factory with full wage paid. The factory provided dormitory for workers, they also could choose to live in their own house. No movement restriction area in the factory, they were voluntary to participate in overtime works. Interviewed workers indicated that no wage and ID card was withheld by the factory.</p> <p>工厂建立了无强迫劳动的程序文件，所有员工都可以自由终止劳动关系并拿到全额报酬。工厂有给员工提供了宿舍，员工可以自由选择回家住宿。车间没有设置限制活动区域，员工可以自由加班。员工表示没有发生扣押工资和身份证件的情况。</p>	
Remarks from Auditee: None	
Performance Area 12 : Protection of the Environment	
Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A	Deadline date:16/12/2020
GOOD PRACTICES: None	
AREAS OF IMPROVEMENT: <p>The factory had established environmental management policy and procedures which included environment impact assessment, conformity assessment regards to environmental law, waste management, environment issue grievance, etc. The factory obtained environmental impact assessment report and approval from government department. Based on onsite observation, no obvious waste was released to factory surrounding during its production activities, no pollution was observed. The factory provided environmental protection knowledge training for workers.</p> <p>被审核方有建立环境政策，其中包括环境影响的评估，环保法规符合性识别评估，废弃物的管理，环保问题申诉等。工厂有获得建设项目的环评报告和政府部门的批复意见。工厂生产过程没有发现对周边环境排放明显的废弃物，没有发现污染情况。工厂有给员工提供了环保知识的培训。</p> <p>12.1 - The factory had conducted environment impact assessment for the factory boundary, but the assessment did not include its production impact to other factories in the industrial park. In accordance with performance area 12: Protection of the environment. 12.1</p> <p>工厂有对周边环境进行环境影响评估，但没有评估其生产活动对园区内其他工厂影响。依据执行领域12：环境保护 12.1</p>	
Remarks from Auditee: The factory management agreed the finding and no other comment.	

Performance Area 13 : Ethical Business Behaviour

Full Audit [Audit Id - 195058] Audit Date: 15/10/2020 PA Score: A

Deadline date:16/12/2020

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory had written procedures on Ethical Behaviour, which included prohibition of corruption, extortion or embezzlement, or any form of bribery, fraud and investigation of unethical behaviors etc. The factory had conducted the assessment on the potential ethic risks. During the audit, accurate records were provided for review, including payroll records, attendance records, certificates and reports. The effective business license was provided for review.

工厂已经建立了书面化的商业道德程序，其中包括风险评估，不正当收益，商业欺诈，不道德行为的调查等。被审核方对潜在的商业道德风险进行了风险评估。审核期间提供了准确的记录查看，包括工资考勤文件、证件和报告等。工厂有获得有效的营业执照。

- 13.4 -** It was noted that the factory had established personal privacy protection procedure, such as personal information privacy, financial privacy, etc, but trainings on personal privacy protection procedure was not provided to all employees. In accordance with Performance Area 13: Ethical Business Behaviour 13.4

审核发现尽管工厂建立了个人隐私保护程序，例如个人信息隐私、财务隐私等，但并未向所有员工提供个人隐私保护方面程序的培训。根据执行领域13：道德商业行为 13.4

Remarks from Auditee:

The factory management agreed the finding and no other comment.

Summary

Audit Type	Date	Audit Id	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Full Audit	15/10/2020	195058	B	B	A	A	B	D	A	A	A	A	A	A	A	C

Producer Photos



External photo(s) of the production unit(s)
Attendance recorder.JPG



External photo(s) of the production unit(s)
BSCI COC.JPG



External photo(s) of the production unit(s)
Canteen building.JPG



External photo(s) of the production unit(s)
Canteen.JPG



External photo(s) of the production unit(s)
Dormitory building.JPG



External photo(s) of the production unit(s)
Emergency light and exit sign.JPG



External photo(s) of the production unit(s)
Emergency light testing.JPG



External photo(s) of the production unit(s)
Evacuation plan.JPG



External photo(s) of the production unit(s)
Eyewash station.JPG



External photo(s) of the production unit(s)
Factory name.JPG



External photo(s) of the production unit(s)
Finished goods.JPG



External photo(s) of the production unit(s)
Fire alarm testing.JPG



External photo(s) of the production unit(s)
Fire alarm.JPG



External photo(s) of the production unit(s)
Fire extinguishers.JPG



External photo(s) of the production unit(s)
Fire facility inspection record.JPG



External photo(s) of the production unit(s)
Fire hydrant testing.JPG



External photo(s) of the production unit(s)
Fire hydrant.JPG



External photo(s) of the production unit(s)
First aid kit.JPG



External photo(s) of the production unit(s)
Mask and earplugs for workers.JPG



External photo(s) of the production unit(s)
Material warehouse.JPG



External photo(s) of the production unit(s)
Mixing.JPG



External photo(s) of the production unit(s)
Molding.JPG



External photo(s) of the production unit(s)
No smoking sign.JPG



External photo(s) of the production unit(s)
Packing.JPG



External photo(s) of the production unit(s)
Potable water.JPG



External photo(s) of the production unit(s)
PPE sign.JPG



External photo(s) of the production unit(s)
Production building and factory gate.JPG



External photo(s) of the production unit(s)
Raw material warehouse.JPG



External photo(s) of the production unit(s)
Suggestion box.JPG



External photo(s) of the production unit(s)
Testing.JPG



External photo(s) of the production unit(s)
Toilet paper and sanitizer.JPG



External photo(s) of the production unit(s)
Toilet.JPG



External photo(s) of the production unit(s)
Warning sign.JPG

Auditee :	Better Care Plastic Technology Co., Ltd.
Audit Date From :	19/10/2020
Audit Date To :	20/10/2020
Expiry Date of the Audit :	Please refer to the producer profile in the amfori BSCI platform
Auditing Company :	BureauVeritas
Auditor's Name(s) :	Vera Wang(Lead), Andy Lu
Auditing Branch (if applicable) :	



This is an extract of the on line Audit Report. The complete report is available in the amfori BSCI Platform.
Access www.bsciplatform.org, for entitled users only.

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Rating Definitions



Rating	A combination of ratings per Performance Area where:	Consequence																																							
A Very Good	<ul style="list-style-type: none">Minimum 7 Performance Areas rated ANo Performance Areas rated C, D or E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr></table>	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	B	B	B	A	A	A	A	A	A	A	A	B	B	B	B	B	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	A	A	A	A	A	A	A																													
A	A	A	A	A	A	A	A	A	A	B	B	B																													
A	A	A	A	A	A	A	A	B	B	B	B	B																													
B Good	<ul style="list-style-type: none">Maximum 3 Performance Areas rated CNo Performance Areas rated D or E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td></tr><tr><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td></tr></table>	A	A	A	A	A	A	B	B	B	B	B	B	B	A	A	A	A	A	B	B	B	B	B	B	B	C	B	B	B	B	B	B	B	B	B	B	C	C	C	The auditee has the level of maturity to maintain its improvement process without the need for a follow-up audit.
A	A	A	A	A	A	B	B	B	B	B	B	B																													
A	A	A	A	A	B	B	B	B	B	B	B	C																													
B	B	B	B	B	B	B	B	B	B	C	C	C																													
C Acceptable	<ul style="list-style-type: none">Maximum 2 Performance Areas rated DNo Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>C</td><td>C</td><td>C</td><td>C</td></tr><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td></tr><tr><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td></tr></table>	A	A	A	A	A	A	A	A	A	C	C	C	C	A	A	A	A	A	B	B	B	B	C	C	C	D	C	C	C	C	C	C	C	C	C	C	C	D	D	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	C	C	C	C																													
A	A	A	A	A	B	B	B	B	C	C	C	D																													
C	C	C	C	C	C	C	C	C	C	C	D	D																													
D Insufficient	<ul style="list-style-type: none">Maximum 6 Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>D</td><td>D</td><td>D</td></tr><tr><td>A</td><td>A</td><td>A</td><td>B</td><td>B</td><td>B</td><td>C</td><td>C</td><td>C</td><td>D</td><td>D</td><td>D</td><td>E</td></tr><tr><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	A	A	A	A	D	D	D	A	A	A	B	B	B	C	C	C	D	D	D	E	D	D	D	D	D	D	D	D	E	E	E	E	E	The auditee needs follow up to support its progress. Following the completion of the audit, the auditee develops a Remediation Plan within 60 days.
A	A	A	A	A	A	A	A	A	A	D	D	D																													
A	A	A	B	B	B	C	C	C	D	D	D	E																													
D	D	D	D	D	D	D	D	E	E	E	E	E																													
E Unacceptable	<ul style="list-style-type: none">Minimum 7 Performance Areas rated E These are three examples: <table><tr><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>A</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>A</td><td>A</td><td>B</td><td>B</td><td>C</td><td>D</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr><tr><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td><td>E</td></tr></table>	A	A	A	A	A	A	E	E	E	E	E	E	E	A	A	B	B	C	D	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E	amfori BSCI Participants shall closely oversee the auditee's progress as the producer may represent a higher risk than other business partners.
A	A	A	A	A	A	E	E	E	E	E	E	E																													
A	A	B	B	C	D	E	E	E	E	E	E	E																													
E	E	E	E	E	E	E	E	E	E	E	E	E																													
Zero Tolerance	A Zero Tolerance Issue was identified (see amfori BSCI System Manual Part V – Annex 5: amfori BSCI Zero Tolerance Protocol)	Immediate actions are required. The amfori BSCI Zero Tolerance Protocol is to be followed.																																							

Main Auditee Information



Name of producer :	Better Care Plastic Technology Co., Ltd.		
DBID number :	404438		
Audit ID :	195260		
Address :	FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY, Shijiazhuang		
Province :	Hebei	Country :	China
Management Representative :	Xiaoling Li		
Contact person:	Xiaoling li	Sector :	Non-Food
Industry Type :		Product group :	
Product Type :	Nitrile Gloves		

Audit Details



Audit Range :	<input checked="" type="checkbox"/> Full Audit	<input type="checkbox"/> Follow-up Audit
Audit Scope :	<input checked="" type="checkbox"/> Main Auditee	<input type="checkbox"/> Main Auditee & Farms
Audit Environment :	<input checked="" type="checkbox"/> Industrial	<input type="checkbox"/> Agricultural <input type="checkbox"/> Small Producer
Audit Announcement :	<input checked="" type="checkbox"/> Fully-Announced	<input type="checkbox"/> Fully-Unannounced <input type="checkbox"/> Semi-Announced
Random Unannounced Check (RUC) :	No	
Audit extent (if applicable) :	none	
Audit interferences or contingencies (if applicable) :	none	
Overall rating :	C	
Need of follow-up :	Yes	If YES, by : 20/10/2021

Rating per Performance Area (PA)

PA 1	PA 2	PA 3	PA 4	PA 5	PA 6	PA 7	PA 8	PA 9	PA 10	PA 11	PA 12	PA 13
B	B	A	A	B	D	A	A	A	A	A	B	A

Executive summary of audit report

Factory name: Better Care Plastic Technology Co., Ltd 河北鸿泽塑胶科技有限公司
 Factory address: FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY, Shijiazhuang Hebei - China
 深泽县工业园区 (府前西路)
 Business license number: 911301286920575093

The factory was established on July 10, 2009, it was mainly manufacturing nitrile gloves. The main production activities in the factory were mixing, forming, inspection and packing.

Per factory management interview, there was no peak season in the factory. Their capacity was 2,200,000,000 pcs per year.

The entire factory was consisted of one flat (part of 2F) production building, one flat (part of 3-storey) production building, one 6-storey dormitory building, one 2-storey canteen (idle).

The construction area used by auditee was about 54,630.37 S.Q meters.

There were totally 482 employees in the factory, including 55 non-production employees and 427 production employees. There were 183 male employees and 299 female employees. The youngest employee worked in the factory was 22 years old.

Production workers' working hours were recorded by face scan system with detailed time in and time out information. There was only one shift for office employees, it was from 08:00 to 12:00 and 13:30 to 17:30, three shifts for production employees, and it was from 00:00-08:00, 08:00-16:00, and 16:00-00:00. All workers were paid in hourly rate at the 20th day of next month by bank transfer.

According to the payroll and attendance records of 22 sample employees from Dec 2019, 22 sample employees from May 2020 and 22 sample employees from Aug 2020, it was noted that the regular wage of all sampled employees in these months was minimum RMB 11.25 per hour, the local minimum wage was RMB 1680 per month equivalent to RMB9.66/hour since Nov 1, 2019. All sampled employees were paid with 150% and 200% of regular wages for their work on weekdays and rest days respectively, which was in line with statutory requirement. No overtime works were noted in statutory holidays.

Additional 5 attendance records were sampled in Sep 2020 for working hour verification. The sampled records indicated that employees' maximum overtime hours was 0 hour a weekday, 8 hours a rest day, 0 hour a holiday, 8 hours a week and 40 hours a month in the testing months. The maximum weekly working hours were 48 hours. The longest consecutive working days were 6 days in the testing periods.

According to the social insurance payment receipt of Aug 2020 provided by factory management, it was noted that only 77 out of 482 employees (16%) were provided with unemployment, maternity and medical insurance, 133 out of 482 employees (28%) were provided with pension insurance and 482 out of 482 employees (100%) were provided with injury insurance. But not all workers were provided with all kinds of social insurance.

The attendance records were cross-checked against production records, attendance records, payroll records and confidential interviews, no inconsistencies regarding working hours were found.

At the end of the audit, a closing meeting was held with the factory representatives. All of the findings were disclosed and discussed and a corrective action plan was explained to the factory representatives, Mrs. Li Xiaoling / Vice GM and Mrs. Song Hongye / Worker Representative agreed with the findings and signed the corrective action plan.

Opening meeting factory representatives (name and titles)

Mr. Zhao Lipeng / Office director;

Mr. Li Ming / Safety director;

Mrs. Xu Lihua / QA director;

Mrs. Song Hongye / Worker Representative;

Remark:

1. There was no contractor used by the auditee, which makes the contractor license/permit not applicable.

2. There was no agency used by the auditee, which makes the agency labor contract not applicable.

3. The Government waivers were not applicable in the auditee.

4. The Collective bargaining agreements were not applicable in the auditee.

5. Audit Company: Bureau Veritas Consumer Products Service

Audit Company APSCA Number: 11600002

Lead Auditor Name: Vera Wang

APSCA Auditor Registered Number: RA 21700004

Member Auditor Name: Andy Lu

APSCA Auditor Registered Number: RA 21701159

Ratings Summary



Auditee's background information			
Auditee's name :	Better Care Plastic Technology Co., Ltd.	Legal status :	Limited company
Local Name :	河北鸿泽塑胶科技有限公司	Year in which the auditee was founded :	2009
Address :	FUQIAN XI ROAD WEST DISTRICT OF SHENZE INDUSTRIAL BASE, SHENZE COUNTY,	Contact person (please select) :	Xiaoling li
Province :	Hebei	Contact's Email :	renmin@honggray.com.cn
City :	Shijiazhuang	Auditee's official language(s) for written communications :	Chinese
Region :	North East Asia	Other relevant languages for the auditee :	None
Country :	China	Website of auditee (if applicable) :	None
GPS coordinates :	N38°18'97", E115°17'93"	Total turnover (in Euros) :	43091394.00
Sector :	Non-Food	Of which exports % :	90.00
Industry :		Of which domestic market % :	10.00
If other, please specify :	Nitrile Rubber	Production volume :	2,200,000,000 pcs/annually
Product Group :		Production cost calculation :	Yes
If other, please specify :	Nitrile Rubber Products	Lost time injury calculation cost :	No
Product Type :	Nitrile Gloves		

Auditee's employment structure at the time of the audit		
Total number of workers :	482	Total number of workers in the production unit to be monitored (if applicable) :
		0
	MALE WORKERS	FEMALE WORKERS
Permanent workers	183	299
Temporary workers	0	0
In management positions	34	21
Apprentices	0	0
On probation	0	0
With disabilities	0	0
Migrants (national citizens)	1	0
Migrants (foreign citizens)	0	0
Workers on the permanent payroll	183	299
Production based workers	149	278
With shifts at night	149	278
Unionised	0	0
Pregnant	-	0
On maternity leave	-	0

Finding Report



Performance Area 1 : Social Management System and Cascade Effect

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee partially respected the requirement of this performance area. The auditee established an effective management to implement the BSCI Code of Conduct, and appointed a senior manager (Mrs. Li) to ensure that the BSCI values and principles were followed in a satisfactory manner. However, there was still a gap between the factory and amfori BSCI requirements in the following aspects. For example, the factory did not plan production capacity rationally, resulting in overtime exceeding legal requirements. 整体观察表明,受审核方部分尊重这个执行领域的要求。被审核方已经建立了执行BSCI行为守则的有效管理体系,并委派了高级经理(李女士)以确保其充分遵循BSCI价值和原则要求。发现工厂在系统执行方面和amfori BSCI要求仍有差距。比如:工厂没有合理规划生产能力,导致加班时间超过法律要求。

- 1.4 -** The factory had established the production capacity assessment procedure, but they had not assessed production capacity, workers' overtime working hours exceeded local law's requirement. This violated Performance Area 1: Social Management System and Cascade Effect 1.4
工厂已建立生产能力评估程序,但还未进行生产能力评估,导致员工的加班时间超过法规要求。根据执行领域1:社会管理体系和级联效应 1.4

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 2 : Workers Involvement and Protection

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee partially respected the requirement of this performance area. Workers are freely and publicly to elect worker representative for once a year, the recent selected worker representative on Jan 4, 2020 and meeting on Sep 4, 2020. Employees could report grievance via suggestion box, hotline or email anonymously. With regard to the reported cases, the HR or worker representative would take time to handle the issues and no retaliation would be made. The factory had provided relevant documents for review. But based on those evidence, the main auditee partially respected this principle because defects were identified in this performance area. Follow findings listed in detailed information.

整体观察表明,受审核方部分尊重这个执行领域的要求。员工每年至少有一次公开选举员工代表,最近一次员工代表选举是在2020年1月4日,最近一次会议举行在2020年9月4日。同时员工可以通过意见箱和邮箱来匿名申诉。对于所有上报的案例,工厂人事部门会负责后续事宜调查和处理,举报员工不会被打击报复。相关文件都有保留和提供查看。但是基于满意的证据,被审核方部分遵守本原则,具体详见审核发现。

- 2.4 -** The factory had provided the social responsibility requirement and BSCI COC training for workers, however, the workers did not completely know the requirements of Amfori BSCI Codes per employee interview. This violated Performance Area 2: Workers Involvement and Protection 2.4.
工厂有给员工提供了社会责任要求和BSCI COC 培训,但是根据员工访谈员工并不完全了解Amfori BSCI守则的要求。根据执行领域2:工人参与和保护2.4
- 2.5 -** The established grievance mechanism did not include all interested parties, it was only applicable for internal part. In accordance with Performance Area 2: Workers Involvement and Protection 2.5.
工厂建立的申诉机制没有包含所有利益相关方,只是对工厂内部适用。根据执行领域2:工人参与和保护2.5

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 3 : The rights of Freedom of Association and Collective Bargaining

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee respected the requirement of this performance area. The auditee respect the right of workers to form and to bargain collectively, there were no isolated employee representatives, no discrimination, and the auditee encourage to enforce the communication between worker representative and workers.

整体观察表明,受审核方尊重这个执行领域的要求。工厂尊重员工推举代表和协商参与工厂事务的权利,工厂没有孤立员工代表,没有区别对待,工厂还鼓励员工代表多与员工沟通。

Remarks from Auditee:

None

Performance Area 4 : No Discrimination

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee respected the requirement of this performance area. The factory had established related non-discrimination policy and provided related training to all employees on Jan 13, 2020. All interview employees, esp. female interviewees told auditor there was no discrimination in the factory.

整体观察表明, 受审核方尊重这个执行领域的要求。工厂建立了明确的反歧视政策并且清楚地通过培训告知员工, 最近一次培训是在2020年1月13日。所有受访员工, 尤其是女性都向审核员反映没有歧视。

Remarks from Auditee:

None

Performance Area 5 : Fair Remuneration

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee partially respected the requirement of this performance area. The factory respected the local law requirements, and the wage related regulations were posted and clearly communicated to all employees. however, the factory management also admitted that they provided all 5 types of social insurances to part of employees. the factory did not conduct any survey or calculation of the local living wage.

整体观察表明, 受审核方部分尊重这个执行领域的要求。工厂遵守当地关于工资和福利的要求, 并且把相关法规要求张贴出来, 并且通过员工手册和开会让员工知晓。然而, 工厂为部分的员工提供5种社会保险, 工厂没有完成最低生活需求工资的调查和计算。

5.4 - It was noted that the factory did not have the sense to evaluate the local living wage, and they did not conduct any survey or calculation of the local living wage before the audit. In accordance with Performance Area 5: Fair Remuneration 5.4

工厂没有意识去评估当地的最低生活需求工资, 也没有在审核前完成最低生活需求工资的调查和计算。根据执行领域5: 公平报酬 5.4

5.5 - According to the social insurance payment receipt of Aug 2020 provided by factory management, it was noted that only 77 out of 482 employees (16%) were provided with unemployment, maternity and medical insurance, 133 out of 482 employees (28%) were provided with pension insurance and 482 out of 482 employees (100%) were provided with injury insurance. But not all workers were provided with all kinds of social insurance. Workers indicated that they were voluntary to participate in social insurance. Factory management agreed with the issue and would take corrective action as soon as possible. This violated Article 73 of the Labor Law of the People's Republic of China.

根据厂方提供的2020年8月的社会保险缴费单据显示, 工厂为77/482名员工(16%)提供了生育, 失业, 医疗保险, 工厂为133/482名员工(28%)提供了养老保险, 工厂为482/482名员工(100%)提供了工伤保险, 但没有达到全员参保。员工表示是自愿参加社保的, 工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第73条

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 6 : Decent Working Hours

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: D

Deadline date:20/12/2020

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory partially respect this performance area. The factory respected local law related to normal working hours. The factory did not respect the overtime hours policy. The factory had clearly communicated working hour policy to all employees through training. Interviewed employees confirmed that they could choose to overtime working or not.

工厂部分尊重这个执行领域。工厂尊重了基本的正常工作时间规定, 没有尊重加班时间的规定, 工厂向员工传达了工厂关于工作时间的政策。面谈的员工证实加班是自愿的。

6.2 - According to the payroll and attendance records of 22 sample employees from Dec 2019, 22 sample employees from May 2020, 22 sample employees from recent paid month Aug 2020 and 5 records from unpaid full month of Sep 2020, it was noted that 22 out of 22 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in May 2020, which was not in compliance with the legal requirement; 22 out of 22 sample population employees worked in excess of 36 overtime hours per month (i.e. 40 hours) in Aug 2020, which was not in compliance with the legal requirement. All employees interviewed represented that they were voluntarily to work overtime and the production workload was acceptable. Factory management agreed with the issue and would take corrective action as soon as possible. This Violated Article 41 of the Labor Law of the PRC.

根据工厂提供的工资考勤记录, 抽样2019年12月22名员工, 2020年5月22名员工, 发薪月份2020年8月22名员工和未发薪月份2020年9月5名员工, 显示 22/22名员工在2020年5月的加班时间为40小时, 超过每月加班时间不能超过36小时的法律规定; 22/22名员工在2020年8月的加班时间为40小时, 超过每月加班时间不能超过36小时的法律规定。访谈员工表示自愿加班, 工作强度也可以接受。工厂同意该问题并表示尽快改善。根据《中华人民共和国劳动法》第41条

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 7 : Occupational Health and Safety

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:20/11/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The overall observation showed that the auditee partially respected the requirement of this performance area. The auditee established fire safety policy, the emergency evacuation plan. The factory conducted twice fire drills each year on Oct 21, 2019 and May 25, 2020. All employees participated in the fire drill. The factory conducted both day and night shifts fire drills to ensure that all workers and all shifts participated in the fire drill. The auditee basically complied with occupational health and safety (OHS) regulations. Further, the auditee provided safety training to employees. However, some health and safety issues were noted onsite.

整体观察表明,受审核方部分尊重这个执行领域的要求。被审核方建立了消防程序文件,应急预案等,对员工进行安全培训等。工厂每年进行两次消防演习分别在2019年10月21日和2020年5月25日。所有员工均参加了消防演习,工厂进行了白天和夜间的消防演习,确保所有工人,所有班次均参与演习。被审核方基本遵守了适合其业务活动的职业健康与安全法规。但被审核方现场仍然有一些健康安全问题的点。

7.1 - It was noted that no specific full-time or part-time safety production management personnel was assigned in the factory, which with 482 employees for production. In accordance with Article 21 of Law of the People's Republic of China on Production Safety
审核员发现工厂的生产员工人数为482人,并未配备专职或者兼职的安全生产管理人员。根据《中华人民共和国安全生产法》第二十一条

7.3 - It was noted that the risk assessment for safe, healthy and hygienic working conditions was not conducted sufficiently. The risk assessment did not cover all production activities, workplaces, machinery, equipment, chemicals, tools and processes and regular monitoring and testing. In accordance with Performance Area 7: Occupational Health and Safety-7.3
工厂为车间岗位进行风险评估不充分。风险评估没有涵盖所有生产活动、生产车间、机器、设备、化学品、工具和过程,没有包括定期监控和检测。根据执行领域7:职业健康和安全-7.3

7.6 - It was noted that one employee working in the forming workshop did not wear earplugs provided by the factory. The factory had established PPE procedure and provided PPE training for employees. Factory management agreed with the issue and would take corrective action as soon as possible. In accordance with Article 42 of Law of the People's Republic of China on Production Safety.
审核员发现工厂成型车间1名员工没有佩戴工厂提供的耳塞。工厂制定了PPE的程序,并为员工提供了PPE培训。工厂同意该问题并表示尽快改善。根据《中华人民共和国安全生产法》第42条。

7.11 - The factory management was unable to provide the fire acceptance check of one flat (part of 3-storey) production building for review. The total construction of all buildings were about 20300.47 square meters. The factory had installed sufficient fire extinguishers and fire hydrants in the buildings. Remark: The entire factory was consisted of one flat (part of 2F) production building, one flat (part of 3-storey) production building, one 6-storey dormitory building, one 2-storey canteen. In accordance with Article 13 of the Construction Project Fire Safety Supervision and Management Regulation. In accordance with Article 24 of the Construction Project Fire Safety Supervision and Management Regulation (Extract)
厂方未能提供1栋1层局部三层的生产楼的消防验收合格证明。总的建筑面积约为20300.47平方米。工厂在厂房安装了足够的灭火器和消防栓。备注:工厂有1栋1层局部2层的生产厂房,1栋1层局部3层的生产厂房,1栋6层的宿舍,1栋2层的餐厅。根据《建设工程消防监督管理规定》第13条根据《建设工程消防监督管理规定》第24条(节选)

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 8 : No Child Labour

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The factory fully respect this performance area. The factory established its child labor forbidden policy. The factory had conducted relevant training for all workers on Jan 13 2020. It was noted that the HR related clerk had to check the ID and age during the hiring process. Through management interview, worker representative interview and employee interview, all knew the child labor forbidden policy and confirmed no child labor in the factory. The youngest employee was 22 years old.

工厂充分尊重这个执行领域。工厂建立了禁止童工政策。工厂为所有的员工在2020年1月13日进行了培训。负责招聘的相关HR人员知道他们必须严格核实新员工的年龄。通过员工、员工代表和管理层访谈都证实清楚的知晓禁止童工政策并且确定工厂没有童工。最小的工人是22岁。

Remarks from Auditee:

None

Performance Area 9 : Special protection for young workers

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None

AREAS OF IMPROVEMENT:

The factory fully respect this performance area. There were not young workers in this factory. However, the factory had established related policies to ensure young workers' working time and not to contact with hazardous materials and harmful job. Worker representative stated that the factory held training and meetings to pay attention to young workers issues.

工厂充分尊重这个执行领域。审核发现工厂没有未成年工。但工厂建立了完整的未成年工保护政策,包括工作时间和禁止未成年工接触有毒化学品和有害工种等等。员工代表还表示,会举行定期的会议,来提醒未成年工问题。

Remarks from Auditee:

None

Performance Area 10 : No Precarious Employment

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

Based on satisfactory evidence, the main auditee fully respects this principle because: The factory had established clear recruit policies to respect local law requirements. Confirmed through employee and employee representative interview, they need to sign standard labor contracts with factory and they kept one labor contract.

基于令人满意的证据, 被审核方充分尊重BSCI的本条原则, 工厂建立了清楚地招聘程序来遵守当地的法规要求。通过员工和员工代表面谈, 确认所有员工进厂时必须签标准的劳动合同, 并且他们自己都留有一份合同。

Remarks from Auditee:

None

Performance Area 11 : No Bonded Labour

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

Based on satisfactory evidence, the main auditee fully respects this principle because: The factory established policies to forbidden bonded labour. Confirmed through employee and employee representative interview, no physical or verbal abuse was noted with the factory.

基于令人满意的证据, 被审核方充分尊重BSCI的本条原则, 工厂建立了禁止强迫员工政策。通过员工和员工代表面谈, 确认工厂不存在体罚和口头侮辱。但通过员工访谈, 审核员发现工厂员工对工厂相关的惩戒条款不了解。

Remarks from Auditee:

None

Performance Area 12 : Protection of the Environment

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: B

Deadline date:20/12/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The main auditee partial respects this principle because: The overall observation showed that the auditee basically fulfilled the requirement of this performance area. The auditee continuously identified the significant impacts and environmental implications associated to its activity, and established the proper procedure to ensure integration of local environmental law into the business performance. The assessment did not include its production impact to other factories in the industrial park.

被审核方部分尊重BSCI的本条原则, 整体观察表明, 受审核方基本满足这个区的要求。被审核方持续识别其商业活动的重大影响及对环境造成的后果, 并且建立了合适程序来确保其商业模式中结合了当地环境法规。但是, 工厂没有评估其生产活动对园区内其他工厂影响。

12.1 - The factory had conducted environment impact assessment for the factory boundary, but the assessment did not include its production impact to other factories in the industrial park. In accordance with performance area 12: Protection of the environment. 12.1

工厂有对周边环境进行环境影响评估, 但没有评估其生产活动对园区内其他工厂影响。依据执行领域12: 环境保护 12.1

Remarks from Auditee:

The factory agreed the finding and no other comment.

Performance Area 13 : Ethical Business Behaviour

Full Audit [Audit Id - 195260] Audit Date: 19/10/2020 PA Score: A

Deadline date:20/12/2020

GOOD PRACTICES:

None.

AREAS OF IMPROVEMENT:

The main auditee partial respects this principle because: The factory had established its ethic policy and none of any act of corruption, or any form of bribery in its activity was noticed during this audit. Training and meeting were regularly held, especially for the business and sourcing departments. The factory had established personal privacy protection procedure, but trainings on personal privacy protection procedure was not provided to all employees.

被审核方部分尊重BSCI的本条原则, 工厂制定了相关的廉政政策并且在审核过程中并没有发现任何腐败或贿赂的商业行为。工厂举办定期的会议和培训给相关的人员, 尤其重点是业务和采购部门。工厂已经制定了员工隐私的保护程序, 但是没有提供相关的培训给所有员工。

13.4 - It was noted that the factory had established personal privacy protection procedure, such as personal information privacy, financial privacy, etc, but trainings on personal privacy protection procedure was not provided to all employees. In accordance with Performance Area 13: Ethical Business Behaviour 13.4

审核发现尽管工厂建立了个人隐私保护程序, 例如个人信息隐私、财务隐私等, 但并未向所有员工提供个人隐私保护方面程序的培训。根据执行领域13: 道德商业行为 13.4

Remarks from Auditee:

The factory agreed the finding and no other comment.

Summary



Audit Type	Date	Audit Id	PA1	PA2	PA3	PA4	PA5	PA6	PA7	PA8	PA9	PA10	PA11	PA12	PA13	Overall Rating
Full Audit	19/10/2020	195260	B	B	A	A	B	D	A	A	A	A	A	B	A	C

Producer Photos



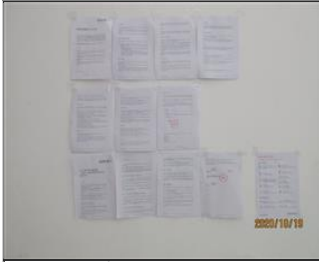
External photo(s) of the production unit(s)
7.6 not using earplug.JPG



External photo(s) of the production unit(s)
assembly point.JPG



External photo(s) of the production unit(s)
attendance machine.JPG



External photo(s) of the production unit(s)
BSCI COC.JPG



External photo(s) of the production unit(s)
canteen.JPG



External photo(s) of the production unit(s)
dormitory inside.JPG



External photo(s) of the production unit(s)
drinking water machine.JPG



External photo(s) of the production unit(s)
electrical box.JPG



External photo(s) of the production unit(s)
emergency light and exit sign testing.JPG



External photo(s) of the production unit(s)
emergency light and exit sign.JPG



External photo(s) of the production unit(s)
evacuation plan.JPG



External photo(s) of the production unit(s)
eye-washing machine.JPG



External photo(s) of the production unit(s)
factory building.JPG



External photo(s) of the production unit(s)
factory gate.JPG



External photo(s) of the production unit(s)
factory name.JPG



External photo(s) of the production unit(s)
finished warehouse.JPG



External photo(s) of the production unit(s)
fire alarm testing.JPG



External photo(s) of the production unit(s)
fire alarm.JPG



External photo(s) of the production unit(s)
fire extinguisher.JPG



External photo(s) of the production unit(s)
fire hydrant testing.JPG



External photo(s) of the production unit(s)
first aid box.JPG



External photo(s) of the production unit(s)
forming.JPG



External photo(s) of the production unit(s)
inspecting.JPG



External photo(s) of the production unit(s)
mixing.JPG



External photo(s) of the production unit(s)
no smoking sign.JPG



External photo(s) of the production unit(s)
occupational hazardous notification card.JPG



External photo(s) of the production unit(s)
packing.JPG



External photo(s) of the production unit(s)
raw material warehouse.JPG



External photo(s) of the production unit(s)
road name.JPG



External photo(s) of the production unit(s)
suggestion box.JPG



External photo(s) of the production unit(s)
toilet.JPG