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Application for a Module B Type-Examination Certificate

In accordance with the Personal Protective Equipment Regulation (EU) 2016/425 and or Regulation 2016/425 on personal protective equipment, as amended to apply in GB. Hereafter referred to as the PPE Regulation.

This application and the subsequent certification will only address the obligations under the PPE Regulation.
It is the responsibility of the manufacturer to ensure that all other legislative requirements and claims, including those relating to shelf life are met.

Please note that all relevant sections of this application should be completed in full. Failure to complete all relevant sections shall result in the rejection of this application.

Please indicate which Notified Body and or Approved Body this application relates. Where the application is for both EU and UKCA type examination then please tick both.

SATRA Technology Europe Limited Notified Body 2777	**EU Type Examination**	☒
SATRA Technology Centre Limited Approved Body 0321	**UKCA Type Examination**	☐

Guidance on the completion of this form

Application type	Tick to indicate application type	Sections to be completed	Submission requirements
All applications		Section 1 Section 7	• Completed and signed application form
Initial type-examination certificate	☐	Section 2 Section 6	• Example of product (s) • Complete technical documentation as per Annex III of the PPE Regulation. See guidance below for required content • Completed module C2/D application, where applicable
Review of existing type-examination certificate	☐	Section 3	• Example of products (s) where significant changes have been identified. • Amendments to technical documentation
Transfer of existing type-examination certificate	☐	Section 4 Section 6	• Example of product (s) where not previously seen by SATRA. • Copy of the approved technical documentation as per Annex III of the PPE Regulation. See guidance below for required content • Copy of certificate to be transferred • Completed module C2/D application, where applicable
Own brand manufacturer/extension type-examination certificate	☒	Section 5 Section 6	• Copy of OBM proposed artwork for user information, product marking and packaging. • Completed module C2/D application, where applicable

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Guidance on the technical documentation required by Annex III of the PPE Regulation

The information below has been copied from Annex III of the PPE regulation and is intended to provide guidance on the content of technical documentation (often referred to as the technical file) that is required to be submitted as part of the type examination application. SATRA can provide upon request a template technical file to aid with the collation of the required documentation.

a) A complete description of the PPE and of its intended use;
b) An assessment of the risks against which the PPE is intended to protect;
c) A list of the essential health and safety requirements that are applicable to the PPE;
d) Design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies, and circuits;
e) Any explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
f) The references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
g) Where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements; the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
h) Reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
i) A description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
j) A copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
k) For PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE based on the approved basic model;
l) For PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

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Section 1 – Applicant details

Section 1.1 Applicant
Details of the applicant to whom the certificates are to be issued, or in the case of an extension application the holder of the main type-examination certificate.

Company Name	**Shijiazhuang Hongray Group Co., Ltd.**		
Address Line 1	South Tongda Road, East District Jinzhou City,Hebei,052260,China		
Address Line 2			
City	Jinzhou	**Country**	China
County/State/Province	Hebei	**Postal Code / ZIP**	052260
Telephone	8617732123968	**Email**	renmin@hongray.com.cn
Contact Name	RENMIN	**Position**	QA

All correspondence relating to this application shall be with the above-named applicant, unless specifically stated below.

Section 1.2 Correspondence
I request that correspondence relating to this application is to be shared with the following company(ies)/contact(s):

Company Name	Contact Name	Email Address
Setino Hungary Kft	LIU JIN	Grace@setino.com

Where additional correspondence has been requested then this shall be on a shared basis.

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Section 1.3 – Invoice details (to be completed if different to the applicant in section 1.1)
Details of the company that is responsible for paying all fees and to whom the invoice shall be issued. Correspondence shall only be with the applicant listed in section 1.1 plus any additional contacts provided in section 1.2.

Company Name	Setino Hungary Kft		
Relationship to applicant	Customer		
Address Line 1	Budapest, Száva u. 4B, 1107		
Address Line 2			
City	Budapest	**Country**	Hungary
County/State/Province	Hungary	**Post Code / ZIP**	1107
Telephone	+36704065340	**Email**	Grace@setino.com
Contact Name	LIU JIN	**Position**	Manager Assistant

I have read and agree to the applicable declarations listed under section 7 of this form.			
Signature	SETINO HUNGARY KFT. 1107 Budapest, Száva u. 4/B Adószám: 13337634-2-42	**Date**	2023.6.8
Print Name	LI LI	**Position**	General Manager

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Section 2 – Application for initial type-examination certificate

Details of the product(s) to be certified

Product Reference (1)	Product Description	Product Standard (s) (2)

Notes

1) The reference, code, or name by which products can be uniquely identified.
2) The product standard to which certification is sought. If a harmonised or designated standard does not exist or is not been fully used then reference shall be made to the section of the technical file where this has been documented and justified.

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Section 3 - Application for review of existing type examination

Details of and reason(s) of the certificate to be reviewed

Certificate Number(s) (1)	**Reason for review** (2)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)
	Choose an item.
	Details of the change(s)

Please submit all amendments to technical documentation relating to the above certificate(s) as well as additional test reports and photographs where applicable with this application.
Please list all changes that you wish to be considered as part of this application. Only these changes shall be considered.

Where the application relates to expiry of a certificate and there have been no modifications or changes to the approved technical documents or products since the issue of the type examination certificate(s), (e.g., design, materials, suppliers, sub-components/assemblies, production locations) then please write “no changes”

Where there is an Own Brand Manufacturer (OBM) (extension) certificate associated with any of the above listed certificates then consideration shall be given to their ongoing validity and where appropriate an extension application completed and submitted.

Notes
(1) Please include the numbers of all certificates that require review.
(2) Please select the option that relates to the reason for the review being required.

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Section 4 – Application for transfer of existing type-examination

Details of the certificate(s) to be transferred, including where not SATRA details of the issuing body.

Certificate Number	Product Reference [1]	Name of Notified or Approved body that issued certificate (if not SATRA)

Have there been any modifications or changes to the approved technical documents or products since the issue of the type examination certificate(s)? (e.g., design, materials, suppliers, sub-components/assemblies, production locations)	Yes	☐	No	☐
If yes, then please provide further details of the changes and or modifications				

Notes

1) The reference, code, or name by which products can be uniquely identified.

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Section 5 – Application for Own Brand/Extension of existing type-examination

Section 5.1 Extension certificate details (Company to receive the extension certificate)

Company Name	Setino Hungary Kft		
Address Line 1	Budapest, Száva u. 4B, 1107		
Address Line 2			
City	Budapest	**Country**	Hungary
County/State/Province	Hungary	**Postal Code / ZIP**	1107
Telephone	+36704065340	**Email**	grace@setino.com
Contact Name	LIU JIN	**Position**	Manager Assistant

Section 5.2 – Certificate details

Original certificate number(s)	Original certificate product reference(s)	Extension (OBM) product reference(s)
2777/14615-03/E00-00	NPF3001-3006 Violet Blue NPF5001-5006 White	Disposable Nitrile Gloves, Powder-free Color: Violet Blue XS: NPF3001 S: NPF3002 M: NPF3003 L: NPF3004 XL: NPF3005 XXL:NPF3006

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Section 5.3 Extension application declaration.

To be signed by the company to whom the extension type-examination certificate will be issued.

I, the undersigned:

1) Confirm that the extension certificate(s) will only be used to support the affixation of the CE or UKCA mark to products that have been supplied by the holder of the Module B Type Examination Certificate(s) referenced in Section 1 above and declared by them to have been manufactured in accordance with the technical documentation associated with the referenced Module B type-examination certificate(s) in section 5.2.
2) Confirm that for Category III products, a formal application regarding Module C2 or Module D assessment, as appropriate has been established with a Notified or Approved Body. (Note this could be based on an existing application between the company in Section 1 and a Notified or Approved Body)
3) Agree to provide copies of the proposed product marking and user information as intended for the products covered by the extension certificate(s).

I have read and agree to the declarations listed above and within section 7 of this form.			
Signature	SETNO HUNGARY KFT. 1107 Budapest, Szávay u. 4/B Adószám: 13337634-2-42	**Date**	2023.6.8
Print Name	LI LI	**Position**	General Manager

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Section 6 – Ongoing conformity

To be completed for category III products only (as defined in Annex I of the PPE Regulation)
Please tick and complete one of the 4 following options

Option 1	Module C2 with SATRA	☒
Option 2	Module D with SATRA (Module D not currently in place with SATRA)	☐
Option 3	Module D with SATRA (Module D currently in place with SATRA)	☐
Option 4	Module C2 or D with another Notified or Approved body (i.e., Not SATRA) Please include Notified or Approved body number	☐

Where a Notified or Approved Body other than SATRA is selected for ongoing conformity then it should be noted that SATRA CANNOT approve the use of the Notified or Approved Body number on marking, user information or packaging. The applicant is required to seek approval directly from the body listed above. SATRA reserves the right to ask for evidence of approval.

Where options 1 or 2 are selected a separate application shall be provided, this shall be required to be completed and returned prior to the type examination certificate being issued.

Definition of products that fall within Category III as per Annex I of the PPE Regulation

a) substances and mixtures which are hazardous to health;
b) atmospheres with oxygen deficiency;
c) harmful biological agents;
d) ionising radiation;
e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
f) low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less;
g) falling from a height;
h) electric shock and live working;
i) drowning;
j) cuts by hand-held chainsaws;
k) high-pressure jets;
l) bullet wounds or knife stabs;
m) harmful noise.

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Section 7 – Declaration

1) I declare that an application for an initial Module B type-examination certification for the product(s) listed in this form has NOT been made to any other Notified or Approved Body under the terms of the PPE Regulation;
2) I understand that all technical documentation shall be reviewed at the same time. SATRA cannot accept requests to review or comment on individual documents outside of this formal review.
3) I agree to provide an example of the product(s) listed in this form as part of the initial application plus as many samples as required for testing purposes identified as part of the certification process and where SATRA is the test lab;
4) I confirm that samples comply with the innocuousness requirements of Annex II of the PPE Regulation;
5) I confirm that I have read, understood, and agree to abide by the content of the certification agreement included as Appendix 1 of this document;
6) I declare that SATRA have not been involved in the design process for the product(s) listed in this form;
7) I agree to comply with all obligations of a manufacturer as detailed in Article 8 of the PPE Regulation (and as copied out under section 5 of the certification agreement);
8) I agree that technical information and documents relating to this application may be shared internally within the SATRA group of companies;
9) I agree to address all findings identified within SATRA's review report(s) within 3 months of the date of issue of the report;
10) I agree that failure to address all findings within the required timeframe shall be assumed by SATRA as a wish to cancel this application which shall result in closure of the associated SATRA reference number, at which point, an invoice shall be issued for the full certification cost. Any associated payments received in relation to this application are non-refundable and non-transferable. Please note that upon cancellation, any product samples submitted to SATRA in relation to this application shall be disposed;
11) I agree that any request to resume a cancelled application shall require the submission of a new application.

To be completed by the applicant as listed in section 1.1.

Signature		**Date**	2023.6.7
Print Name	RENMIN	**Position**	QA

Please return the completed application form, together with a copy of your technical documentation to ppe@satra.com.

Guidance relating to the submission of samples will be provided upon receipt of this application by SATRA.

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Appendix 1 – Certification agreement

1. General

1.1 By signing this application form, the applicant (hereafter known as the 'Client') shall accept the application and Certification Agreement as a legally binding contract between SATRA Technology Centre Limited and or SATRA Technology Europe Ltd (hereafter referred as 'SATRA') and the 'Name of company' as stated in the 'Applicant Details' on Page 1 of the Application Form.

1.2 Where referenced within this document the SATRA Group of companies refers to SATRA Technology Centre Limited, SATRA Technology Europe Limited and SATRA Technology Services (Dongguan) Limited.

1.3 EU or UKCA module B Type Examination work will not be carried out for any Client until a fully completed and signed Application Form (and Certification Agreement) has been received by SATRA.

a) and or reinstatement of a certificate
b) Reassessment due to changes in the management system or products certified
c) Compliance with any subpoena for documents or testimony relating to activities undertaken by SATRA

2. Client Responsibilities

The Client shall:

2.1 Undertake to pay all agreed fees and costs charged in conjunction with this application and where applicable to provide free of charge any samples required for testing purposes.

Additional fees may be incurred for work not included within the quote provided and for work required where non-conformances are identified. These may include, without limitation, costs arising from:

a) Repeats of any part of the certification, due to the registration procedures and rules not being met
b) Additional work due to suspension, withdrawal and or reinstatement of a certificate
c) Reassessment due to changes in the management system or products certified
d) Compliance with any subpoena for documents or testimony relating to activities undertaken by SATRA

2.2 Inform SATRA, without delay, of any changes that may affect its ability to conform with the certification requirements, including changes significantly affecting the product's design or specification, or changes in the standards to which compliance of the product is relevant, or in the case of any other information indicating that the product may no longer comply with the requirements of the certification scheme.

Examples of changes may include the following:

a) the legal, commercial, organisational status or ownership,
b) organisation and management (e.g., key managerial or technical staff),
c) modifications to the product or the production method,
d) contact address and manufacturing sites,
e) major changes to the quality management system.

Where changes have taken place, the Client shall not release CE or UKCA marked products until the appropriate changes to the certified product, as agreed by SATRA and the Client, have been implemented.

2.3 Where applicable, provide access to certified products for surveillance activities.

2.4 Ensure that the certified product shall continue to fulfill the requirements of the product certification (e.g., levels or classifications achieved as part of the certification process).

2.5 Make all necessary arrangements for:

a) the conduct of the evaluation and surveillance (if required), including provision for examining documentation and records, and access to the relevant equipment, location(s), area(s), personnel, and the Client's subcontractors;
b) the investigation of complaints;
c) the participation of observers, if applicable.

2.6 Provide any applicable information regarding known or potential hazards likely to be encountered by SATRA personnel as a result of handling or coming in to contact with submitted samples or during visits in order to allow SATRA to comply with Health and Safety legislation

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2.7 Take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the Module B Type Examination Certificate and with the relevant basic requirements of the PPE Regulation.

2.8 Ensure that any claims regarding certified products are consistent with the scope of product certification with respect to the identification of:

a) the product(s), process (es) or services(s) for which the certification is granted;
b) the applicable certification scheme; and,
c) the standard(s) and other normative document(s) (including date of publication) to which the product(s); process(es) or service(s) has been judged to comply.

2.9 Not use its product certification in such a manner as to bring SATRA into disrepute and does not make any statement regarding its product certification that SATRA may consider misleading or unauthorised.

2.10 Upon suspension, withdrawal, or termination of certification, the Client discontinues its use of all advertising matter that contains any reference thereto and acts as required by the certification scheme (e.g., the return of certification documents) and takes any other required measure.

2.11 Only provide copies of the certification documents to others, if the documents are reproduced in their entirety.

2.12 In referring to its product certification in communication media such as documents, brochures or advertising, the Client complies with the requirements of SATRA or as specified by the certification scheme.

2.13 Comply with any requirements that may be prescribed in the certification scheme relating to the use of marks of conformity, and on information related to the product. These being:

2.13.1 The CE or UKCA Mark can only be applied to stationery and publicity material which relates to the products for which certification has been granted. This can include the internet, brochures, advertisements etc. We would advise any Client to contact us prior to printing if there is any doubt regarding the intended use. The misuse of the CE, UKCA or other marks could result in the issue of a requirement to withdraw offending items.

2.13.2 Where possible the minimum height of the CE or UKCA mark must be no less than 5mm and shall only be increased in proportion.

2.13.3 The CE, UKCA or other mark may not be used in any way that may be interpreted as misleading nor shall the client make any misleading statements regarding its certification

2.13.4 The use of SATRA's Notified Body or Approved body number after the CE or UKCA mark is restricted to those products defined as Category III Products and where SATRA is responsible for Module C2 or Module D. However, it may be used on user information of all certified products as a means of identifying SATRA as the type approval body and the Module C2 or D body.

2.13.5 Upon suspension or withdrawal of its certification, The Client shall discontinue its use of the CE or UKCA mark as directed by SATRA and shall amend all advertising matter when the scope of registration has been reduced. The Client shall ensure that the CE, UKCA or other marks are not used in such a manner that would bring SATRA into disrepute and lose public trust.

2.14 Uses certification only to indicate that products are certified as being in conformity with the PPE Regulation and where applicable specified standards.

2.15 Shall confirm that the samples submitted for any testing required as part of the certification process shall be representative of the product to be certified in respect of all its characteristics taken together, and be made from production tools and assembling methods used for the production run.

2.16 Retains a record of all non-conformities and complaints relating to certification requirements of the certified product(s) and makes these records available to SATRA when requested, and:

a) takes appropriate action with respect to such complaints about any deficiencies found in products that affect compliance with the requirements for certification;
b) documents the action taken.

2.17 Retain the EU or UKCA Certificate of Conformity (or a copy of it) for a minimum of 10 years after the product to which it relates is last placed on the market

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3. SATRA Responsibilities

3.1 SATRA shall inform the Client of any changes that may affect the validity of the product certification.

3.2 After confirming the acceptance of the application, the SATRA Assessor shall discuss and agree with the Client the responsibility for carrying out the various tasks according to the requirements of Annex II of the PPE Regulation as applicable. Where testing is required, this shall be carried out in accordance with SATRA Technology Centre Limited's ISO 17025 Quality system and procedures. SATRA reserves the right to sub-contract testing, where this is required then this shall be agreed with the Client.

3.3 SATRA shall carry out the certification process against an agreed product standard (s) or specification (s) where possible. The normal route shall be to use an English language version of the appropriate European Harmonised, or UK designated standard. National forewords to such standards will not normally be considered unless specifically requested by the Client. Other standards or technical specifications may be used, where this is deemed necessary then it shall be by mutual agreement with the Client. Whichever option is chosen it shall satisfy all the relevant requirements of the PPE Regulation. This shall also include appropriate test data to demonstrate that the materials used to construct the products do not contain substances that may cause harm and that they are in compliance with the current requirements of all applicable product standards as well as the current version of Annex XVII of the EU and or UK REACH Regulation.

3.4 SATRA shall retain copies of technical files for a minimum of 10 years after the product is last placed on the market and/or the EU or UKCA Module B Type Examination certificate is cancelled, withdrawn or expires, whichever comes sooner. Such documentation shall be made available to the Surveillance Authorities upon demand.

3.5 Where review of an existing certificate is requested, the Assessor shall send the Client an appropriate application form for completion and return. On return of the completed application form, the Assessor shall decide on whether reduced Certification Procedures may be undertaken and shall document the decision.

3.6 Where an extension to an existing certificate is requested, the Assessor shall send the Client an appropriate application form for completion and return.

3.7 Where SATRA becomes aware that a registered Client has misused a certificate, schedule, logo or accreditation mark, the Client shall be required to ensure that the misuse is rectified. Incorrect references to the certification system or misleading use of information found in advertisements, catalogues etc. shall be dealt by suitable means including corrective action, publication of the transgression and, if necessary, legal action.

3.8 Suspension, termination, and withdrawal of certificates

3.8.1 Where a certificate is suspended, terminated, or withdrawn then the Client has the right to appeal. The appeal shall be received in writing, by SATRA, within twenty-eight working days of the Client having being informed of the intention to suspend, withdraw, or terminate the certificate.

3.8.2 The outcome of an appeal shall be final and binding on both parties and no counter claim by either party shall be accepted. Where an appeal is successful, the Clients costs may be reimbursed at the discretion of SATRA.

3.8.3 Suspension of certificates.

3.8.3.1 A Clients EU or UKCA Module B Type Examination Certificate may be suspended for the following reasons:

- Contravention of SATRA's rules and regulations relating to product certification;
- Where effective corrective action is not implemented within an agreed timescale against a major non-compliance found during a surveillance visit.
- Where significant non-homogeneity is highlighted during on-going surveillance.

3.8.3.2 SATRA shall inform the Client in writing that their certificate has been suspended, the reason(s) for the suspension and the actions required to reinstate the certificate.

3.8.3.3 SATRA shall inform the appropriate notifying authority when a Client's certificate has been suspended.

3.8.3.4 If product certification is reinstated after suspension, SATRA shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified.

3.8.3.5 If a decision to reduce the scope of product certification is made as a condition of reinstatement, SATRA shall make all necessary modifications to formal product certification documents, public information, authorisations for use of marks, etc., in order to ensure the reduced scope of product certification is clearly communicated to the Client and clearly specified in product certification documentation and public information.

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3.8.4 Withdrawal or termination of certificates

3.8.4.1 A certificate shall be withdrawn 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 the Directive or Regulation as applicable;
- The Client fails to settle their financial obligations to SATRA;
- The Client fails to effectively implement the actions agreed following the suspension of a certificate;
- Actions taken by the Client during their business activities that would bring SATRA and / or the Product Certification Scheme into disrepute;
- The Client does not wish to continue with certification;
- The Client goes out of business.

3.8.4.2 SATRA shall inform the Client in writing that their certificate has been withdrawn, the reason(s) for the withdrawal and any actions required.

3.8.4.3 SATRA shall inform the appropriate notifying authority when a Client's certificate has been withdrawn.

3.9 Confidentiality

3.9.1 The results of Product Certification activities shall be treated by SATRA as confidential. Results obtained shall only be passed to third parties with the permission of the Client that originally commissioned it, except for requests from enforcement and surveillance authorities.

Note: SATRA reserves the right to share information relating to certification within the SATRA Group of companies unless advised otherwise.

3.10 Complaints and Appeals

3.10.1 Upon receipt of a complaint or an appeal which relates to product certification activities, the Business area head or their nominated deputy shall deal with it in accordance with SATRA's complaints and appeals procedure.

3.10.2 Where the complaint or appeal relates to the on-going conformity of a product certified by SATRA, it is possible that any agreed remedial actions may involve recalling non-compliant products in which case SATRA shall require documented evidence of such a recall.

3.10.3 Complainants raising issues regarding a) products not being CE or UKCA -marked when they should be or b) EU or UKCA Type Examination certificates issued by other Notified or Approved Bodies shall be directed to the appropriate enforcement authority.

3.10.4 SATRA shall only accept written appeals received within twenty-eight days of the client being informed of the decision that gave rise to the appeal.

3.10.5 Full details of the SATRA Complaints and Appeals procedure are available on request.

3.11 SATRA shall retain in its archive for the period required by the relevant accreditation body all materials relating to the certificate. After which SATRA shall dispose of said materials unless instructed otherwise by the Client. All fees for carrying out such instructions will be invoiced to the Client.

4.0 SATRA Requirements

4.1 Any test reports submitted to SATRA in support of EU or UKCA type examination shall meet the following criteria:

a) Reports shall reflect state of the art and be as current as possible, where reports are older than 5 years (60 months) then SATRA reserves the right to request additional supporting documentation, such as more recent check test data;

b) Where not undertaken by SATRA, all testing and reporting shall be carried out by a laboratory that is independent and impartial to any economic operator of the finished product and considered as being competent to conduct the work. Accreditation of a laboratory to ISO 17025 by a National Accreditation Body that is recognised by INAB or UKAS (see ILAC website) for the work undertaken will be taken as evidence of competence as long as it can also demonstrate that it has knowledge of, and access to, any appropriate recommendation for use sheets and guidance papers endorsed by the European Commission or UK Government. In the absence of such accreditation, a report will be accepted only when competence has been demonstrated to the satisfaction of SATRA, via an audit visit and, where judged necessary, check testing.

Note, in either case if the laboratory is not a Notified or Approved Body, SATRA may commission limited check testing on safety critical properties;

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c) Innocuousness test data which has been requested in addition to that required by the main European Harmonised or UK Designated Standard or performance specification. These additional innocuousness tests (i.e., not detailed in the product standard) need not be carried out by SATRA or an ISO 17025 accredited facility but it will be necessary to submit actual test data (declarations of conformity are not acceptable).

d) Reports shall contain where possible the following information:

(i) sample references given in any test report shall be the same as those detailed in the technical file,
(ii) reference to the manufacturer and manufacturing site(s),
(iii) identification of the organisation and personnel responsible for the test,
(iv) identification of the product(s) in accordance with the relevant technical specification,
(v) date(s) samples were received and the date(s) testing was undertaken,
(vi) details of samples received and the sampling procedure if applicable,
(vii) testing methods and procedures used according the relevant technical specification,
(viii) the results of all testing carried out, including analysis of these where relevant,
(ix) registration number of the Notified Body (when relevant),
(x) signature of the person authorised to sign such test reports;

e) The Test Report shall indicate compliance of the product(s) with the relevant clauses of the harmonised standard (s).

4.2 Copies of all test Reports used as part of the certification process shall be submitted to SATRA. Copies of Test Reports that form part of any on-going monitoring procedure should be retained by the manufacturer and made available on request.

4.3 All test reports submitted as part of the certification process shall, where applicable, include information relating to the use of uncertainty of measurement. When evaluating the suitability of results and reports SATRA will, where applicable to safety critical aspects of the product, take uncertainty of measurement into account. SATRA reserves the right to reject reports where the uncertainty of measurement cannot be determined for those tests/properties deemed by SATRA to be safety critical.

4.4 Where a technical file is required as part of the certification process then it shall include at least the following:

a) name & address of the manufacturer;
b) name and address of the Authorised representative in the EU (if relevant);
c) full description(s) of the product(s) included within the technical file, including specifications, annotated drawings and comprehensive photographs of all styles;
d) full details of all materials and components used in the construction of the product (s) including specifications, and supplier details (name and postal address);
e) quality control procedures, and where appropriate, a copy of the ISO9001 certificate for the manufacturing site(s), this should include a description of the control and test facilities at the manufacturing site(s) that are in place in order to check compliance of production with the harmonized standards / technical specifications to ensure ongoing compliance;
f) details of proposed packaging and product marking, including label artwork;
g) copy (ies) of all applicable user information sheets, these shall comply with the requirements of the agreed product standard;
h) check list showing compliance with the applicable health and safety requirements, Annex II of the PPE Regulation;
i) all applicable test reports, references to materials on submitted test reports must correspond with those in the material specifications.

4.5 SATRA reserves the right to request additional supporting documentation including further testing, where the certification process becomes protracted.

5.0 Article 8 of the PPE Regulation – Obligations of manufacturers

5.1 When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

5.2 Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU or UKCA declaration of conformity referred to in Article 15 and affix the CE or UKCA marking referred to in Article 16.

5.3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

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5.4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised or Designated standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately considered.

When deemed appropriate regarding the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

5.5 Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

5.6 Manufacturers shall indicate, on the PPE, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

5.7 Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible, and legible.

5.8 The manufacturer shall either provide the EU or UKCA declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

5.9 Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details of the non-conformity and of any corrective measures taken.

5.10 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

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USER INFORMATION

CE 2777

These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE REGULATION 2016/425 and have been shown to comply with this Regulation through the Harmonised European Standard(s): EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016

Product reference:

	XS	S	M	L	XL	XXL
Refernce#	NPF3001	NPF3002	NPF3003	NPF3004	NPF3005	NPF3006

Disposable nitrile gloves (Violet Blue)

Sizes available: XS(5-6), S(6-7), M(7-8), L(8-9), XL (9-10), XXL (10-11)

Intended Use:
The gloves are intended for protective purpose that is worn on the user's hands to make protection. It is ambidextrous and single use. Gloves have specified chemical protection function. The products are suitable for use in various fields such as garden, lab etc.

Performance and limitation of use –This product has been tested and achieved the following performance levels:

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN ISO 374-4:2019 Degradation%**
40% Sodium Hydroxide (K)	6	-58.9
30% Hydrogen Peroxide (P)	2	-0.8
37% Formaldehyde (T)	4	1.9

EN ISO 374-1:2016+A1:2018 /Type B

KPT

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	**Pass**
Protection against Viruses	**Pass**

EN ISO 374-5:2016

Virus

EN ISO 374-1:2016+A1:2018 Permeation levels are based on breakthrough times as follows:

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

EN ISO 374-4:2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical:

EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen."

"This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals"

"The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture."

"It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."

"When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"

"Before usage, inspect the gloves for any defect or imperfections."

Storage and transport: When not in use, store the product in a well-ventilated area away from extremes of temperature

Glove performance quoted is based on laboratory data and may not reflect the actual duration of protection in the workplace due to other factors influencing the performance such as temperature, abrasion, degradation etc.)

The glove does not contain any substances that are known to cause allergies.
The Gloves have no mechanical protection offered.
For single use only, do not littering.
Check for damage before use, do not use damaged gloves

Donning:

1. Remove all hand and wrist jewelry, and wash the hands before donning.
2. Place the gloves on the prepared work surface.
3. The user puts a glove on his/her dominant hand by grabbing it with the other hand, remembering to only touch the inside of the gloves, and slipping it over the dominant hand until it reaches finder level.
4. The wearer uses the gloved dominant hand to slip the other glove onto the non-dominant hand.
5. Once both gloves are on, the users can touch the outside of the gloves to ensure a proper fit

Doffing:

1. Using the dominant hand, users start by grabbing the outside of the glove on the non-dominant hand on the palm side near the cuff.
2. Pull the glove off the non-dominant hand and place it in the gloved hand, balling it up.
3. Slip two fingers under the cuff of the other hand glove and carefully peel it off the hand without touching the wrist, turning the remaining glove inside put as it is removed and in turn encasing the first glove.
4. The gloves can be disposed.

The DoC(declaration of conformity) will be shown on website: (www.setino.com)

Notified Body responsible for certification and ongoing conformity:

SETINO™

SATRA Technology Europe Ltd

Bracetown Business Park

Clonee, Dublin

D15 YN2P, Ireland (: 2777)

Product manufactured by: Setino Hungary Kft
Budapest, Szára u. 4B, 1107, Hungary

YYYY-MM

YYMMDD

3years from manufacture date

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi
Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion
Gants d'Examen et de Protection en Nitrile

SETINO®

M | 7-8 | NITRILE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

NITRILE | POWDER-FREE

SETINO®

MEDICAL

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi

CE 2777

M | 7-8 | NITRILE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

NITRILE | POWDER-FREE

Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion
Gants d'Examen et de Protection en Nitrile

TEXTURED

NITRILE | POWDER-FREE

SIZE: M (7-8)

[en] HARSH CHEMICALS: Although good quality nitrile gloves provide an excellent biological barrier, they are not intended for applications involving prolonged, direct exposure to harsh chemicals, where heavy duty or industrial gloves are required. Consult your institution's policies regarding latex allergies. Do not expose this product to any person or known suspected to be sensitive to nitrile manufacturing components before consultation with a physician. Follow your institution's policies for use. For single use only. Store in a cool dry place. Shield open tox from direct sunlight, fluorescent lighting or x-rays.

Test acc. to EN ISO 374-1:2016+A1:2018 Chemical | Level | Test acc. to EN ISO 374-4:2019 Degradation %

40% Sodium hydroxide (K)	6	-58.9
30% Hydrogen peroxide (P)	2	-0.8
37% Formaldehyde (T)	4	1.9

EN ISO 374-1:2016+A1:2018 Permeation levels are based on breakthrough times as follows:
/ Level 1 > 10 min / Level 2 > 30 min
/ Level 3 > 60 min / Level 4 > 120 min
/ Level 5 > 240 min / Level 6 > 480 min

EN ISO 374-5:2016:
Protection against Bacteria and fungi: Pass
Protection against viruses: Pass

SETINO®

NITRILE | POWDER-FREE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

M | 7-8 | NITRILE

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi
Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion
Gants d'Examen et de Protection en Nitrile

NITRILE | POWDER-FREE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

M | 7-8 | NITRILE

Gtmac reference Code: STBLNT35

(01)06948794411340(17)YYMMDD(10)YYMMDD

LATEX-FREI | EINWEG | BEID-HÄNDIG | PUDER FREI | NICHT STERIL

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi
Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion
Gants d'Examen et de Protection en Nitrile

MANUAL DEL USUARIO / MANUALE PER L'USO / USER GUIDE / BENUTZERHANDBUCH / GUIDE DE L'UTILISATEUR

[es] Lavese siempre las manos antes de ponerse los guantes y cada vez que cambie a un neuvo par. **[it]** Lavare sempre le mani prima di indossare i guanti e prima di indossare un nuovo paio. [en] Always wash hands before putting on gloves and each time you change to a new pair. **[de]** Waschen Sie immer die Hände, bevor Sie Handschuhe anziehen und jedes Mal, wenn Sie ein neues Paar wechseln. **[fr]** Lavez-vous toujours les mains avant de mettre vos gants et chaque fois que vous en changez.

[es] Seleccione guantes desechables apropiados para la tarea y su tamaño adecuado. **[it]** Selezionare guanti monouso appropriati per il compito di svolgere e della misura corretta. **[en]** Select disposable gloves appropriate for the task and in your proper size. **[de]** Wählen Sie für die Aufgabe geeignete Einweghandschuhe in der richtigen Größe aus. **[fr]** Choisissez des gants jetables adaptés à la tâche et à votre taille.

[es] Para evitar contaiminacion, cambie de guantes cuando estén sucios, rasgados, o antes de comenzar una tarea diferente. **[it]** Per evitare la contaminazione incrociata, cambiare i guanti quando sono sporchi, usurati o prima di iniziare un compito differente. **[en]** To avoid cross contamination, change gloves when soiled, torn, or before beginning a different task. **[de]** Um Kreuzkontaminationen zu vermeiden, wechseln Sie die Handschuhe, wenn sie verschmutzt, zerrissen oder vor Beginn einer anderen Aufgabe sind. **[fr]** Pour éviter toute contamination croisée, changez de gants lorsqu'ils sont souillés, déchirés ou avant de commencer une autre tâche.

[es] Cambiar de guantes al menos cada cuato horas durante una tarea continua. **[it]** Cambiare i guanti almeno ogni quattro ore durante un compito continuativo.**[en]** Change gloves at least every four hours during a continual task. **[de]** Wechseln Sie die Hand-schuhe mindestens alle vier Stunden während einer kontinuierlichen Aufgabe. **[fr]** Changez de gants au moins toutes les quatre heures lors d'une tâche continue.

AQL 1.0 | TÜVRheinland CERTIFIED | EN 455

EN ISO 374-5:2016 VIRUS | EN ISO 374-1:2016+A1:2018/Type B KPT

LATEX | NON STERILE | CC

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Szava 4/B
1107, Budapest, Hungary

Distributor/Verteiler/Distributore/Distribuidor
SETINO ESPAÑA, S.L.
C/.Maria Moliner 3, Portal 2 - 6°B
03540 Alicante, Spain

SETINO ITALIA S.R.L.
Viale Mazzini, 25
05100 Temi (TR) Italia

Setino Medical Group d.o.o.
Zagrebačka cesta 7
10361 Sesvete (Grad Zagreb) Croatia

[en] Examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

[de] Untersuchungs- und Schutzhandschuhe / Nitril / puderfrei / Einweghandschuhe / bei Beschädigung der Verpackung kann die Qualität des Produktes nicht gewährleistet werden / Länge geeignet für Tätigkeiten, bei denen Handschutz erforderlich ist /

[it] Guanti da esaminazione e protettivi / in nitrile / senza polvere / monouso / la qualita' del prodotto non e' garantita in caso di danneggiamento della confezione / lunghezza adatta per usi che richiedono protezione della mano /

[es] Guantes protectores de examen / de nitrilo / sin polvo / con textura / para un solo uso / la calidad del producto no estará garantizada si se daña el embalaje / longitud adecuada para actividades que requieren protección de las manos /

[fr] Gants d'examen et de protection / nitrile / non poudrés / à usage unique / la qualité du produit n'est pas garantie en cas d'endommagement de l'emballage / longueur adaptée aux activités nécessitant une protection des mains /

[pt] Luvas de diagnóstico e de proteção / de nitrilo / sem pó / descartáveis / caso a embalagem esteja danificada não se garante a qualidade do produto / comprimento adequado para atividades que exigem proteção das mãos

[hu] Vizsgáló- és védőkesztyű / nitril / púdermentes / egyszer használatos / a termék minőségéért nem vállaljuk a felelősséget sérült csomagolás esetén / a termék hossza megfelel olyan munkák elvégzéséhez, ahol fontos a kéz védelme/

[sv] Undersöknings- och skyddshandskar / nitril / puderfria / för engångsbruk / produktens kvalitet kan inte garanteras om förpackningen är skadad / lämplig längd för aktiviteter som kräver handskydd /

[no] Undersøkelses-og vernehansker / nitril / pudderfrie / til engangsbruk / produktkvaliteten kan ikke garanteres ved skadet emballasje / passende lengde til arbeider som krever håndvern /

[fi] Tutkimus- ja suojakäsineet / nitriilikumiset / pieniriskiseen käyttöön / puuterittomat / kertakäyttöiset / tuotteen laatutakuu raukeaa, jos pakkaus on vaurioitunut / pituus sopii käsiensuojausta vaativiin toimintoihin /

[pl] Rękawice diagnostyczne i ochronne / nitrylowe / bezpudrowe / do jednorazowego użycia / jakości produktu nie gwarantuje się w przypadku uszkodzenia opakowania / długość odpowiednia do czynności wymagających ochrony dłoni

[dk] Handsker til undersøgelse og personlig beskyttelse / nitril / uden pudder / til engangsbrug! kvaliteten af produktet kan ikke garanteres i tilfælde af beskadigelse af pakningen / længden tilsvarer de handlinger, som kræver beskyttelse af hænden / işlemler için uygundur /

[es] PRODUCTOS QUIMICOS AGRESIVOS: Aunque los guantes de nitrilo de buena calidad proporcionan una excelente barrera biológica, no son destinados a aplicaciones que implican una exposición directa y prolongada a productos químicos agresivos, donde se requieren trabajos pesados o Se requieren guantes industriales.
PRECAUCIÓN: Los componentes utilizados en la fabricación de guantes de nitrilo pueden causar reacciones alérgicas en algunas personas. No exponga este producto a cualquier persona o sospechosa de ser sensible a los componentes de fabricación de nitrilo antes de consultar con un médico. Siga las políticas de uso de su institución, Para un solo uso, Guardar en un lugar fresco y seco, Proteja la caja abierta de la luz solar directa, la luz fluorescente o los rayos X.

[it] PRODOTTI CHIMICI AGGRESSIVI: Sebbene i guanti in nitrile di buona qualità forniscano una barriera biologica eccellente, non sono da intendersi per applicazioni con esposizione diretta e prolungata a prodotti chimici aggressivi, dove sono richiesti guanti ultraresistenti o industriali.
AVVISO: I componenti utilizzati durante la realizzazione di guanti in nitrile possono causare reazioni allergiche in alcune persone. Si raccomanda di non esporre questo prodotto a persone con sensibilità accertata o presunta a componenti di produzione in nitrile senza consultazione medica, Si raccomanda di seguire le politiche istituzionali in merito all'uso, Non possono essere riutilizzati, Conservare in un luogo fresco e asciutto, Una volta aperta, proteggere la scatola da raggi solari diretti, luci fluorescenti o raggi x.

[de] SCHARFE CHEMIKALIEN: Obwohl qualitativ hochwertige Nitrilhandschuhe eine hervorragende biologische Barriere bieten, sind sie nicht für Anwendungen geeignet, bei denen man über längere Zeit direkt mit aggressiven Chemikalien in Kontakt kommt und schwere oder industrielle Handschuhe erforderlich sind,
VORSICHT: Die zur Herstellung von Nitrilhandschuhen verwendeten Komponenten können bei manchen Menschen allergische Reaktionen hervorrufen. Setzen Sie dieses Produkt keiner Person aus, bei der der Verdacht besteht, dass sie empfindlich auf Bestandteile der Nitrilherstellung reagiert, bevor Sie einen Arzt konsultiert haben, Befolgen Sie die Richtlinien Ihrer Einrichtung für die Verwendung, Nur für den einmaligen Gebrauch, Kühl und trocken lagern, Schützen Sie die offene Box vor direkter Sonneneinstrahlung, fluoreszierender Beleuchtung oder Röntgenstrahlen.

[fr] PRODUITS CHIMIQUES AGRESSIFS: Bien que les gants en nitrile de bonne qualité constituent une excellente barrière biologique, ils ne sont pas destinés aux applications impliquant une exposition directe et prolongée à des produits chimiques agressifs, pour lesquelles des gants industriels ou à usage intensif sont nécessaires.
ATTENTION: Les composants utilisés pour la fabrication des gants en nitrile peuvent provoquer des réactions allergiques chez certaines personnes, N'exposez pas ce produit à une personne dont on soupçonne qu'elle est sensible aux composants utilisés dans la fabrication du nitrile avant d'avoir consulté un médecin, Suivez les politiques d'utilisation de votre institution, A usage unique uniquement, A conserver dans un endroit frais et sec, Protégez la boîte ouverte de la lumière directe du soleil, de l'éclairage fluorescent ou des rayons X.
user information is contained inside the box

MEDICAL		PPE	
MDR 2017/745 EU, 93/42/EEC	Class I.	2016/425 EU	Category III.
EN455-1, EN455-2, EN455-3, EN455-4		EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 21420:2020	
EC REP	Caretechion GmbH Niederrheinstr. 71, 40474 Duesseldorf, Germany		
CH REP	SUNGO Technical Service GmbH Bahnhofstrasse 21,6300 Zug, Switzerland		
MD ISO 15223-1	ASTM D6978		

[en] Declarations of Conformity, [de] Konformitätserklärungen, [it] Dichiarazioni di conformità, [es] Declaración de conformidad, [fr] Déclaration de conformité, [pt] Declaração de conformidade, [hu] Megfelelőségi nyilatkozat, [sv] Deklaraton om överensstämmelse, [no] Konformitetserklæring, [fi] Vaatimustenmukaisuusvakuutus, [pl] Deklaracja zgodności, [hr] Izjava o sukladnosti, [cz] Prohlášení o shodě, [sl] Izjava o skladnosti, [sk] Vyhlásenie o zhode, [ro] Declarație de conformitate, [bg] Декларация за съвместимост на,
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XS (5-6) | S (6-7) | **M (7-8)** | L (8-9) | XL (9-10) | XXL (10-11)

REF NPF 3003

In China hergestellt /
Prodotto in Cina / Made in China

21 PAP

MDR (Medical Device Regulation) | PPE (Personal Protective Equipment) | MD

LOT

6 948794 411340 >

[bg] ръкавици за преглед предлагащи / нитрилне / без пудра / за еднократна употреба / качеството на продукта не е гарантирано в случай на увреждане на опаковката / дължина, подходяща за дейности, изискващи защита на ръцете

[gr] εξεταστικά και προστατευτικά γάντια / από νιτρίλιο / χωρίς πούδρα / ανάλυση επιφάνειας / μιας χρήσης / η ποιότητα του προϊόντος δεν είναι εγγυημένη σε περίπτωση που η συσκευασία είναι κατεστραμμένη / μήκος κατάλληλο για δραστηριότητες που απαιτούν προστασία παλάμιου / σύντανυ τυκου /

[uk] нестерильні / нітрилові / захисні рукавички / не порошкоподібний / оглядові та захисні рукавички / одноразового використання / якість продукту не гарантується у випадку пошкодження упаковки / довжина відповідно до дій, які вимагають охорони долоні руки

[ro] mănuși de examinare și protecție / nitril / fără pudră / de unică folosință / calitatea produsului nu este garantată în cazul deteriorării ambalajului / lungime potrivită pentru sarcini care necesită protecție pentru mâini /

[hr] zaštitne rukavice za pregled / nitrilne / bez pudera / s teksturom / samo za jednokratnu upotrebu / kvaliteta proizvoda ne jamči se u slučaju oštećenja ambalaže / duljina prikladna za aktivnosti koje zahtijevaju zaštitu ruku /

[lv] pārbaudes un aizsargcimdi / nitrils / bez pūdera / tekstūrēts / tikai vienreizējai lietošanai / produkta kvalitāte netiek nodrošināta, ja iepakojums ir bojāts / garums piemērots uzdevumiem, kuriem nepieciešama roku aizsardzība

[tr] koruyucu muayene eldiveni / nitril / pudrasızdır / tek kullanımlıktır / hasarlı paketlerdeki ürünlerin kalitesi garanti edilemez / uzunluk, ellerin korunmasını gerektiren

[ee] uurimis- ja kaitsekindad / nitriil / pulbrivaba / tekstureeritud / ainult ühekordselt kasutatav / toote kvaliteet ei ole garanteeritud, kui pakend on kahjustatud / pikkus sobib käte kaitsmist nõudvate ülesannete jaoks

[lt] apžiūros ir apsaugинės pirštinės / nitrilas / be pudros / tekstūruotos / tik vienkartiniam naudojimui / garmino kokybė nėra užtikrinama, jei pakuotė pažeista / ilgis tinkamas užduotims, kurioms reikia rankų apsaugos

[nl] onderzoeks- en beschermende handschoenen / nitril / poedervrij / gestructureerd / voor eenmalig gebruik / productkwaliteit is niet gegarandeerd als de verpakking beschadigd is / lengte geschikt voor taken waarbij handbescherming vereist is

[cz] diagnostické a ochranné rukavice / nitril / bezpudrové / pro jednorázové použití / kvalitu výrobku nelze zaručit v případě poškození obalu / délka vhodná pro úkony, které vyžadují ochranu rukou /

[sl] diagnostične in zaščitne rokavice / nitril / nepudrane / za enkratno uporabo / kakovost izdelka ni zagotovljena v primeru poškodovane embalaže / dolžina, ustrezna glede na dejavnosti zahtevajoče zaščito rok /

[sk] diagnostické a ochranné rukavice / nitril / bezpráškové / pre jednorazové použitie / kvalitu výrobku nie je možné zaručiť v prípade poškodenia obalu / dĺžka vhodná pre úkony, ktoré vyžadujú ochranu rúk /

[sr|ba] rukavice dijagnostičke i zaštitne / nitrilne / bez pudera / za jednokratno korišćenje / kvalitet proizvoda se ne garantuje u slučaju oštećenja pakovanja / dužina pogodna za aktivnosti koje zahtevaju zaštitu ruku /

[en] Examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi
Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion

NITRILE | POWDER-FREE

NICHT STERIL | PUDER FREI | BEID-HÄNDIG | EINWEG | LATEX-FREI

M | 7-8 | NITRILE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

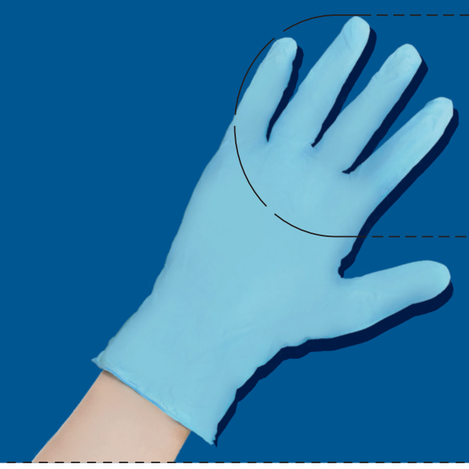
SETINO®

Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi

NITRILE | POWDER-FREE

Nitril-Untersuchungs- und Schutzhandschuhe

Guantes de Nitrilo de Examen y Proteccion



TEXTURED

CE 2777

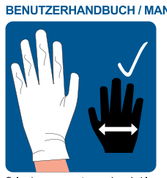
M | 7-8 | NITRILE

100 pieces by weight
HANDSCHUHE / GUANTI / GLOVES

SETINO®
NITRILE | POWDER-FREE
Nitrile Examination and Protective Gloves
Guanti in Nitrile da Esaminazione e Protettivi
Nitril-Untersuchungs- und Schutzhandschuhe
Guantes de Nitrilo de Examen y Proteccion
100 pieces by weight HANDSCHUHE / GUANTI / GLOVES
M | 7-8 | NITRILE

BENUTZERHANDBUCH / MANUALE PER L'USO / USER GUIDE

Lavese siempre las manos antes de ponerse los guantes y cada vez que cambie a un neuvo par. / Lavare sempre le mani prima di indossare i guanti e prima di indossare un nuovo paio. / Always wash hands before putting on gloves and each time you change to a new pair.



Seleccione guantes desechables apropiados para la tarea y su tamaño adecuado. / Selezionare guanti monouso appropriati per il compito di svolgere e della misura corretta. / Select disposable gloves appropriate for the task and in your proper size.

Para evitar contaminacion, cambie de guantes cuando estén sucios, rasgados, o antes de comenzar una tarea diferente. / Per evitare la contaminazione incrociata, cambiare i guanti quando sono sporchi, usurati o prima di iniziare un compito differente. / To avoid cross contamination, change gloves when soiled, torn, or before beginning a different task.

Cambiar de guantes al menos cada cuato horas durante una tarea continua. / Cambiare i guanti almeno ogni quattro ore durante un compito continuativo. / Change gloves at least every four hours during a continual task.

AQL 1.0 | TÜVRheinland CERTIFIED | EN ISO 374-5:2016 VIRUS | EN ISO 374-1:2016+A1:2018/Type B KPT | EN 455 | LATEX | NON STERILE

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

Importer/Importeur/importatore/importador
Setino Hungary Kft.
Száva 4/B
1107, Budapest, Hungary

Distributor/Verteiler/Distributore/Distribuidor
SETINO ESPAÑA, S.L.
C/Maria Moliner, Numero 3 Portal 2,
Planta (6°B 03540 Alicante)

SETINO ITALIA S.R.L.
Viale Mazzini, 25
05100 Temi (TR) Italia

[en] examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

[de] Untersuchungs- und Schutzhandschuhe / Nitril / puderfrei / Einweghandschuhe / bei Beschädigung der Verpackung kann die Qualität des Produktes nicht gewährleistet werden / Länge geeignet für Tätigkeiten, bei denen Handschutz erforderlich ist /

[it] guanti da esaminazione e protettivi / in nitrile / senza polvere / monouso / la qualita' del prodotto non e' garantita in caso di danneggiamento della confezione / lunghezza adatta per usi che richiedono protezione della mano /

[es] guantes protectores de examen / de nitrilo / sin polvo / con textura / para un solo uso / la calidad del producto no estará garantizada si se daña el embalaje / longitud adecuada para actividades que requieren protección de las manos /

[fr] gants d'examen et de protection / nitrile / non poudrés / à usage unique / la qualité du produit n'est pas garantie en cas d'endommagement de l'emballage / longueur adaptée aux activités nécessitant une protection des mains /

[pt] luvas de diagnóstico e de proteção / de nitrilo / sem pó / descartáveis / caso a embalagem esteja danificada não se garante a qualidade do produto / comprimento adequado para atividades que exigem proteção das mãos

[hu] vizsgáló- és védőkesztyű / nitril / púdermentes / egyszer használatos / a termék minőségéért nem vállaljuk a felelősséget sérült csomagolás esetén / a termék hossza megfelel olyan munkák elvégzéséhez, ahol fontos a kéz védelme /

[sv] undersöknings- och skyddshandskar / nitril / puderfria / för engångsbruk / produktens kvalitet kan inte garanteras om förpackningen är skadad / lämplig längd för aktiviteter som kräver handskydd /

[no] undersøkelses-og vernehansker / nitril / pudderfrie / til engangsbruk / produktkvaliteten kan ikke garanteres ved skadet emballasje / passende lengde til arbeider som krever håndvern /

[fi] tutkimus- ja suojakäsineet / nitriilikumiset / pieniriskiseen käyttöön / puuterittomat / kertakäyttöiset / tuotteen laatutakuu raukeaa, jos pakkaus on vaurioitunut / pituus sopii käsiensuojausta vaativiin toimintoihin /

[pl] rękawice diagnostyczne i ochronne / nitrylowe / bezpudrowe / do jednorazowego użycia / jakości produktu nie gwarantuje się w przypadku uszkodzenia opakowania / długość odpowiednia do czynności wymagających ochrony dłoni

[dk] handsker til undersøgelse og personlig beskyttelse / nitril / uden pudder / til engangsbrug/ kvaliteten af produktet kan ikke garanteres i tilfælde af beskadigelse af pakningen / længden tilsvarer de handlinger, som kræver beskyttelse af hånden / ișlemler için uygundur /

PRODUCTOS QUIMICOS AGRESIVOS: Aunque los guantes de nitrilo de buena calidad proporcionan una excelente barrera biológica, no son destinados a aplicaciones que implican una exposición directa y prolongada a productos químicos agresivos, donde se requieren trabajos pesados o Se requieren guantes industriales.

PRECAUCIÓN: Los componentes utilizados en la fabricación de guantes de nitrilo pueden causar reacciones alérgicas en algunas personas. No exponga este producto a cualquier persona o sospechosa de ser sensible a los componentes de fabricación de nitrilo antes de consultar con un médico. Siga las políticas de uso de su institución. Para un solo uso, Guardar en un lugar fresco y seco.

PRODOTTI CHIMICI AGGRESSIVI: Sebbene i guanti in nitrile di buona qualità forniscano una barriera biologica eccellente, non sono da intendersi per applicazioni con esposizione diretta e prolungata a prodotti chimici aggressivi, dove sono richiesti guanti ultraresistenti o industriali.

AVVISO: I componenti utilizzati durante la realizzazione di guanti in nitrile possono causare reazioni allergiche in alcune persone. Si raccomanda di non esporre questo prodotto a persone con sensibilità accertata o presunta a componenti di produzione in nitrile senza consultazione medica. Si raccomanda di seguire le politiche istituzionali in merito all'uso. Non possono essere riutilizzati.

HARSH CHEMICALS: Although good quality nitrile gloves provide an excellent biological barrier, they are not intended for applications involving prolonged, direct exposure to harsh chemicals, where heavy duty or industrial gloves are required.

CAUTION: Components used making nitrile gloves may cause allergic reactions in some people. Do not expose this product to any person or known suspected to be sensitive to nitrile manufacturing components before consultation with a physician. Follow your instutition's policies for use. For single use only.

Kühl und trocken lagern. / Conservare in un luogo fresco e asciutto. / Store in a cool, dry place./

Schützen Sie die offene Box vor direkter Sonneneinstrahlung, fluoreszierender Beleuchtung oder Röntgenstrahlen. / Una volta aperta, proteggere la scatola da raggi solari diretti, luci fluorescenti o raggi x / Shield open box from direct sunlight, fluorescent lighting or x-rays.

user information is contained inside the box

MEDICAL		PPE	
MDR 2017/745 EU, 93/42/EEC	Class I.	2016/425 EU	Category III.
EN455-1, EN455-2, EN455-3, EN455-4		EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN ISO 374-4:2019, EN ISO 374-5:2016, EN ISO 21420:2020	
EC REP	Caretechion GmbH Niederrheinstr. 71, 40474 Duesseldorf, Germany	Product Reference Code: NPF3003	
MD ISO 15523-1	ASTM D6978		

[en] Declarations of Conformity, [de] Konformitätserklärungen, [it] Dichiarazioni di conformità, [es] Declaración de conformidad, [fr] Déclaration de conformité, [pt] Declaração de conformidade, [hu] Megfelelőségi nyilatkozat, [sv] Deklaration om överensstämmelse, [no] Konformitetserklæring, [fi] Vaatimustenmukaisuusvakuutus, [pl] Deklaracja zgodności, [hr] Izjava o sukladnosti, [cz] Prohlášení o shodě, [sl] Izjava o skladnosti, [sk] Vyhlásenie o zhode, [ro] Declarație de conformitate, [bg] Декларация за съвместимост на,

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CE 2777

MDR Class I | PPE Cat. III | MD

6 948794 411340 >

In China hergestellt /
Prodotto in Cina / Made in China

21 PAP

LOT

XS (5-6) | S (6-7) | **M (7-8)** | L (8-9) | XL (9-10) | XXL (10-11)

[bg] ръкавици за преглед предпазващи / нитрилне / без пудра / за еднократна употреба / качеството на продукта не е гарантирано в случай на увреждане на опаковката / дължина, подходяща за дейности, изискващи защита на ръцете /

[gr] εξεταστικά και προστατευτικά γάντια / από νιτρίλιο / χωρίς πούδρα / ανάλογα επιφάνεια / μιας χρήσης / η ποιότητα του προϊόντος δεν είναι εγγυημένη σε περίπτωση που η συσκευασία είναι κατεστραμμένη / μήκος κατάλληλο για δραστηριότητες που απαιτούν προστασία παλάμόνου / ochranu rukou /

[uk] нестерильні / нітрилові / захисні рукавички / не порошкоподібний / оглядові та захисні рукавички / одноразового використання / якість продукту не гарантується у випадку пошкодження упаковки / довжина відповідно до дій, які вимагають охорони долоні руки

[ro] mănuși de examinare și protecție / nitril / fără pudră / de unică folosință / calitatea produsului nu este garantată în cazul deteriorări ambalajului / lungime potrivită pentru sarcini care necesită protecție pentru mâini /

[hr] zaštitne rukavice za pregled / nitrilne / bez pudera / s teksturom / samo za jednokratnu upotrebu / kvaliteta proizvoda ne jamči se u slučaju oštećenja ambalaže / duljina prikladna za aktivnosti koje zahtijevaju zaštitu ruku /

[cz] diagnostické a ochranné rukavice / nitril / nepudrované / pro jednorázové použití / kvalitu výrobku nelze zaručit v případě poškození obalu / délka vhodná pro úkony, které vyžadují ochranu rukou /

[sl] diagnostične in zaščitne rokavice / nitril / nepudrane / za enkratno uporabo / kakovost izdelka ni zagotovljena v primeru poškodovane embalaže / dolžina, ustrezna glede na dejavnosti zaščitenega področja rok /

[sk] diagnostické a ochranné rukavice / nitril / bezpráškové / pre jednorazové použitie / kvalitu výrobku nie je možné zaručiť v prípade poškodenia obalu / dĺžka vhodná pre úkony, ktoré vyžadujú ochranu rúk /

[srlps] rukavice dijagnostičke i zaštitne / nitrilne / bez pudera / za jednokratno korišćenje / kvalitet proizvoda se ne garantuje u slučaju oštećenja pakovanja / dužina pogodna za aktivnosti koje zahtevaju zaštitu ruku /

[en] Examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

[ee] uurimis- ja kaitsekindad / nitriil / pulbrivaba / tekstuuritud / ainult ühekordselt kasutatav / toote kvaliteet ei ole garanteeritud, kui pakend on kahjustatud / pikkus sobib käte kaitsmist nõudvate ülesannete jaoks

[lt] apžiūros ir apsauginės pirštinės / nitrilas / be pudros / tekstūruotos / tik vienkartiniam naudojimui / gaminio kokybė nėra užtikrinama, jei pakuotė pažeista / ilgis tinkamas užduotims, kuriome reikia rankų apsaugos

[nl] onderzoeks- en beschermende handschoenen / nitril / poedervrij / gestructureerd / voor eenmalig gebruik / productkwaliteit is niet gegarandeerd als de verpakking beschadigd is / lengte geschikt voor taken waarbij handbescherming vereist is

[cz] diagnostické a ochranné rukavice / nitril / bezpudrové / pro jednorázové použití / kvalitu výrobku nelze zaručit v případě poškození obalu / délka vhodná pro úkony, které vyžadují ochranu rukou /

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[en] Examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is not ensured if the package is damaged / length suitable for tasks that require hand protection /

EU DECLARATION OF CONFORMITY

1)This declaration of conformity is issued under the sole responsibility of the manufacturer:

Company Name:	Setino Hungary Kft
Address:	Budapest, Száva u. 4B, 1107
Product code:	NPF 3001-3006 (Violet Blue)

2)insert description of the object of declaration

Description of the Product: Disposable Nitrile Gloves (Violet Blue)

3)The object of the declaration descried in point 2 is in conformity with the relevant Union harmonisation legislation: **Personal Protective Equipment Regulation (EU) 2016/425**

4)References to the relevant harmonised standards used, including the date of the standard or references to the other technical specification, including the date of the specification, in relation to which conformity is declared:

Standards/ Technical Specifications applied	ENISO 21420:2020
	ENISO 374-1:2016+A1:2018(KPT) ENISO 374-2:2019 EN16523-1:2015+A1:2018
	ENISO 374-4:2019 ENISO 374-5:2016 Virus

5)Where applicable, the notified body SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland; Notified Body Number: 2777 performed the EU examination (Module B) and issued the EU type- examination certificate (Reference to that certificate)

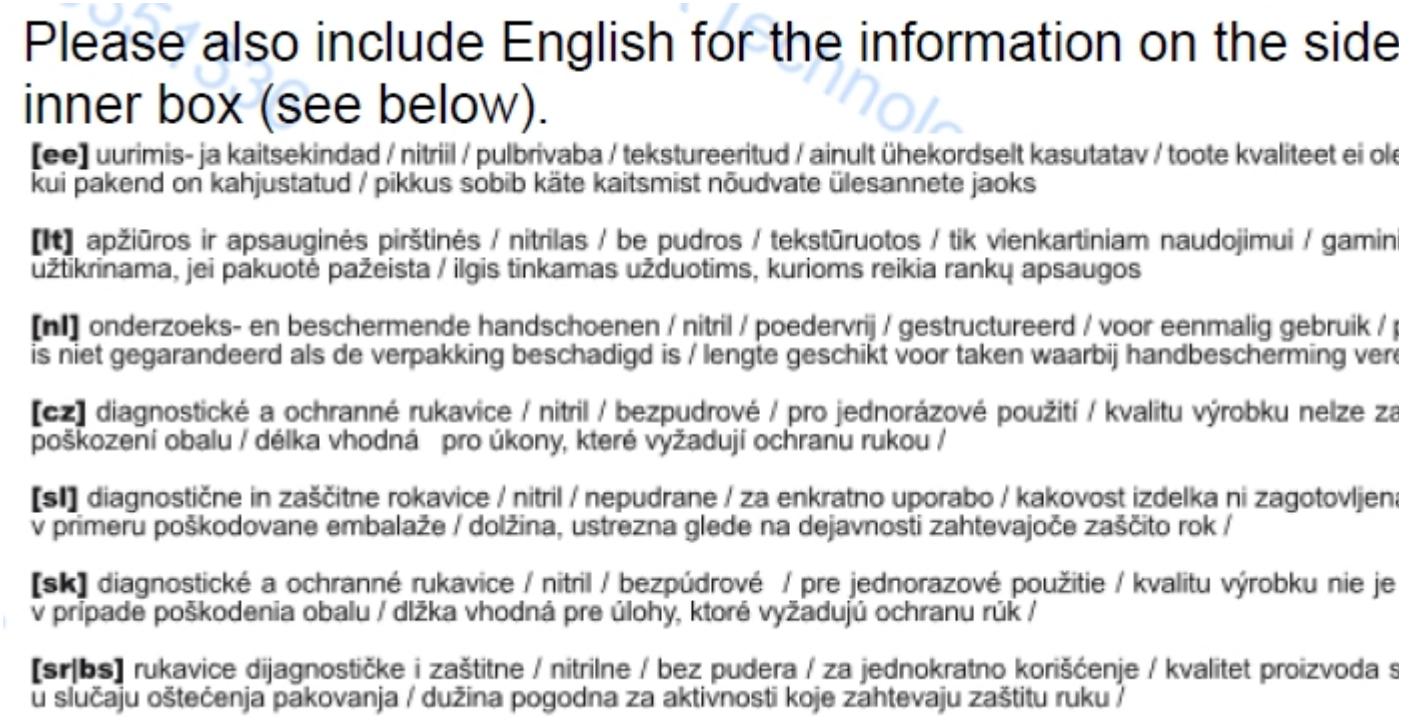
6)Where applicable, the PPE is subject to the conformity assessment procedure (either conformity to type based on internal production control plus supervised product checks at random intervals (module C2) or conformity to type based on quality assurance of the production process (module D under surveillance of the notified body: SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin 15D15 YN2PIreland; Notified Body Number: 2777

Signed for and on behalf of	Setino Hungary Kft SETINO HUNGARY KFT. 1107 Budapest, Száva u. 4/B Adószám: 13337634-2-42
Date of issue	June 08, 2023
Name, function	LI LI, General Manager

Sally Lei

From: renmin@hongray.com.cn
Sent: Tuesday, June 20, 2023 5:40 PM
To: Sally Lei
Cc: Eric Guo; SATRA China Cert
Subject: Re: Re: NPF 3001-3006 / CHC0351046

Sally,



English version has been updated in the inner box as below.

[en] Examination and protective gloves / nitrile / powder-free / textured / for single use only / product quality is n ensured if the package is damaged / length suitable for tasks that require hand protection /

renmin@hongray.com.cn

From: renmin@hongray.com.cn
Date: 2023-06-19 17:45
To: Sally Lei
CC: ericg; SATRA China Cert
Subject: Re: NPF 3001-3006 / CHC0351046

Sally,

证书草稿稍后确认，其他comment的信息更新了。

Confirm the UI SHEET IS SUPPLIED INSIDE THE DISPENSER BOX.

CIMAC reference code :STBKNT35 is product's Item No

renmin@hongray.com.cn

From: Sally Lei

Sally Lei

From: renmin@hongray.com.cn
Sent: Monday, June 19, 2023 5:46 PM
To: Sally Lei
Cc: Eric Guo; SATRA China Cert
Subject: Re: NPF 3001-3006 / CHC0351046
Attachments: ASTMD 6978.pdf; update-artwork 01.pdf; update-artwork 02.pdf

Sally,
证书草稿稍后确认，其他comment的信息更新了。
Confirm the UI SHEET IS SUPPLIED INSIDE THE DISPENSER BOX.
CIMAC reference code :STBKNT35 is product's Item No

renmin@hongray.com.cn

From: Sally Lei
Date: 2023-06-16 11:37
To: renmin@hongray.com.cn
CC: Eric Guo; SATRA China Cert
Subject: NPF 3001-3006 / CHC0351046
Hello Renmin,

请确认附档的证书草稿。

同时请根据审核意见报告修改技术文件，谢谢

Best regards,

Sally Lei
China PPE Certification

**** SATRA Webinar and online resources 网络研讨会及线上资源 https://www.satra.com/resources/ ****
SATRA Technology Services (Dongguan) Limited
东莞赛卓检测技术服务有限公司
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中国广东省东莞市南城区西平宏伟路新中银花园110商铺
www.satra.com / www.satra.cn

From: Emma Kwong <emmak@satrafe.com>
Sent: Monday, June 12, 2023 10:36 AM
To: renmin@hongray.com.cn
Cc: Ting Huang <tingh@satrafe.com>; Eric Guo <ericg@satrafe.com>; Sally Lei <sallyl@satrafe.com>; SATRA China Cert <cert@satrafe.com>
Subject: Re: 3张客户延展--加急 CHC0351045/ CHC0351046/ CHC0351047
Importance: High

Hello Renmin,

January 5, 2021

▪TEST REPORT▪

PN 156884

PHARMACEUTICAL SERVICES

Prepared For:

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

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218

January 5, 2021

Renmin
Shijiazhuang Hongray Group Co., Ltd.

PN 156884

SUBJECT: Permeation testing per ASTM D6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Powder Free Nitrile Examination Gloves – Extended Cuff, Device Identifier Hongray: NEGPF2001-2004, Corresponding Devices ID, NEOBEX: 1530-1021000B-E.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Busulfan, 6 mg/ml (6,000 ppm)	Sigma Aldrich; Lot# BCBZ9160; Expiration 01/2022
Carboplatin, 10 mg/ml (10,000 ppm)	Teva; Lot# 19K11KA; Expiration 11/2021
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	USP; Lot# R116Y0; Expiration 07/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# MKCJ9806; Expiration 01/2022
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	USP; Lot# M1M099; Expiration 02/2021
Docetaxel, 10 mg/ml (10,000 ppm)	LC Labs; Lot# BDC-117; Expiration 01/2025
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Epirubicin HCl, 2 mg/ml (2,000 ppm)	Actavis; Lot# 7U15152; Expiration 10/2020
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fludarabine, 25 mg/ml (25,000 ppm)	USP; Lot# H1K220; Expiration 08/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Gemcitabine, 38 mg/ml (38,000 ppm)	LC Labs; Lot# GMC-105; Expiration 1/6/2025
Idarubicin HCl, 1 mg/ml (1,000 ppm)	Teva; Lot# 31325163B; Expiration 05/2021
Ifosfamide, 50 mg/ml (50,000 ppm)	Baxter Healthcare; Lot# 9A018G; Expiration 01/2022
Irinotecan, 20 mg/ml (20,000 ppm)	USP; Lot# R10230; Expiration 12/2020
Melphalan, 5 mg/ml (5,000 ppm)	USP; Lot# R086P0; Expiration 02/2021
Methotrexate, 25 mg/ml (25,000 ppm)	Teva; Lot# 19F06NB; Expiration 06/2021
Mitomycin C, 0.5 mg/ml (500 ppm)	USP; Lot# R07240; Expiration 07/2021
Mitoxantrone, 2 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 02/2021
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
Rituximab, 10 mg/ml (10,000 ppm)	Hetero Healthcare; Batch# RB1921B; Expiration 08/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 04/2021
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Hospira; Lot# G057139AA; Expiration 03/31/2021

January 5, 2021

Renmin
Shijiazhuang Hongray Group Co., Ltd.

PN 156884

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Busulfan, 6 mg/ml (6,000 ppm)	Distilled Water
Carboplatin, 10 mg/ml (10,000 ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	Distilled Water
Docetaxel, 10 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Epirubicin HCl, 2 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fludarabine, 25 mg/ml (25,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Gemcitabine, 38 mg/ml (38,000 ppm)	Distilled Water
Idarubicin HCl, 1 mg/ml (1,000 ppm)	Distilled Water
Ifosfamide, 50 mg/ml (50,000 ppm)	Distilled Water
Irinotecan, 20 mg/ml (20,000 ppm)	Distilled Water
Melphalan, 5 mg/ml (5,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2 mg/ml (2,000 ppm)	Distilled Water
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Rituximab, 10 mg/ml (10,000 ppm)	Distilled Water
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D6978
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

January 5, 2021

Renmin
Shijiazhuang Hongray Group Co., Ltd.

PN 156884

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths Used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Busulfan, 6 mg/ml (6,000 ppm)	197
Carboplatin, 10 mg/ml (10,000 ppm)	192
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	269
Docetaxel, 10 mg/ml (10,000 ppm)	231
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Epirubicin HCl, 2 mg/ml (2,000 ppm)	233 & 253
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fludarabine, 25 mg/ml (25,000 ppm)	261
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Gemcitabine, 38 mg/ml (38,000 ppm)	202
Idarubicin HCl, 1 mg/ml (1,000 ppm)	257
Ifosfamide, 50 mg/ml (50,000 ppm)	200
Irinotecan, 20 mg/ml (20,000 ppm)	200
Melphalan, 5 mg/ml (5,000 ppm)	260
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2 mg/ml (2,000 ppm)	245
Paclitaxel, 6.0 mg/ml (6,000 ppm)	231
Rituximab, 10 mg/ml (10,000 ppm)	192
ThioTepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

January 5, 2021

Renmin
Shijiazhuang Hongray Group Co., Ltd.

PN 156884

SAMPLE CHARACTERISTICS:

Examination Gloves – Extended Cuff, Device Identifier Hongray: NEGPF2001-2004, Corresponding Devices ID, NEOBEX: 1530-1021000B-E.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Busulfan	0.080	0.076	0.079	0.078
Carboplatin	0.079	0.076	0.081	0.079
Carmustine	0.093	0.082	0.081	0.086
Cisplatin	0.093	0.079	0.081	0.084
Cyclophosphamide (Cytoxan)	0.084	0.079	0.083	0.082
Cytarabine	0.085	0.079	0.088	0.084
Dacarbazine	0.085	0.091	0.078	0.085
Daunorubicin HCl	0.083	0.077	0.092	0.084
Docetaxel	0.083	0.092	0.081	0.085
Doxorubicin HCl	0.081	0.072	0.083	0.078
Epirubicin HCl	0.081	0.074	0.081	0.079
Etoposide	0.083	0.080	0.081	0.081
Fludarabine	0.081	0.073	0.082	0.079
Fluorouracil	0.090	0.074	0.084	0.083
Gemcitabine	0.080	0.073	0.082	0.078
Idarubicin HCl	0.092	0.079	0.081	0.084
Ifosfamide	0.084	0.074	0.081	0.080
Irinotecan	0.081	0.080	0.079	0.080
Melphalan	0.082	0.083	0.094	0.086
Methotrexate	0.081	0.077	0.092	0.083
Mitomycin C	0.079	0.076	0.083	0.079
Mitoxantrone	0.082	0.083	0.076	0.081
Paclitaxel	0.087	0.081	0.083	0.084
Rituximab	0.081	0.081	0.079	0.080
ThioTepa	0.080	0.084	0.081	0.081
Vincristine Sulfate	0.080	0.087	0.079	0.082
Weight/Unit Area (g/m2)	**74.3**			

RESULTS:

Table 5.1 Permeation Test Results on testing of: Powder Free Nitrile Examination Gloves – Extended Cuff, Device Identifier Hongray: NEGPF2001-2004, Corresponding Devices ID, NEOBEX: 1530-1021000B-E.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Busulfan, 6 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Carboplatin, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	33.1 (36.3,34.1,33.1)	1.1 (1.0,1.1,1.1)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation

EXAMINED BY SATRA - DO NOT AMEND

RESULTS cont.:

Table 5.2 Permeation Test Results on testing of: Powder Free Nitrile Examination Gloves – Extended Cuff, Device Identifier Hongray: NEGPF2001-2004, Corresponding Devices ID, NEOBEX: 1530-102 1000B-E.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Cytarabine, 100 mg/ml (100,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Daunorubicin HCl, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Docetaxel, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Epirubicin HCl, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fludarabine, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Gemcitabine, 38 mg/ml (38,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Idarubicin HCl, 1 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Irinotecan, 20 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Melphalan, 5 mg/ml (5,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Methotrexate, 25 mg/ml (25,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitomycin C, 0.5 mg/ml (500 ppm)	>240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Moderate swelling and no degradation
Rituximab, 10 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	68.1 (68.1,76.8,78.1)	0.7 (0.8,0.7,0.6)	Slight swelling and no degradation
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation