



# 石家庄鸿锐集团

## SHIJIAZHUANG HONGRAY GROUP

### EU Declaration of Conformity

#### Factory

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

#### European Representative

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

The undersigned **Shijiazhuang Hongray Group Co., Ltd.**, as manufacturer of:

#### Nitrile disposable gloves

Size	Blue 4.5gram	Black 3.5gram	Blue 3.5gram	White 3.5 gram	Vinyl 5gram
XS	NPF2001	NPF4001	NPF3001	NPF5001	VGPF1001
S	NPF2002	NPF4002	NPF3002	NPF5002	VGPF1002
M	NPF2003	NPF4003	NPF3003	NPF5003	VGPF1003
L	NPF2004	NPF4004	NPF3004	NPF5004	VGPF1004
XL	NPF2005	NPF4005	NPF3005	NPF5005	VGPF1005
XXL	NPF2006	NPF4006	NPF3006	NPF5006	VGPF1006

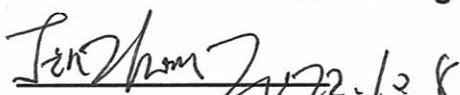
#### BASIC UDI-DI:69487944

We, the manufacturer herewith declare under the sole responsibility that the product concerned complies the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002, Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, EU Regulation 2016/425.

The following standards have been used and in relation to which conformity is declared:  
ISO 13485:2018; ISO 14971:2020; ISO 15223-1:2012; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015;  
EN 455- 4:2010;EN 374-1:2016+A1:2018; EN 374-2:2019; EN 374-4:2019; EN374-5:2016; UNI EN  
16523-1:2015+A1 2018; UNI EN 420:2003+A1:2009.

This EU declaration of conformity has been drafted under sole  
responsibility of

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

  
Place, date 2022.12.8

  
Signature  
QA manager:Wumin