



石家庄鸿锐集团

SHIJIAZHUANG HONGRAY GROUP

EU Declaration of Conformity

Factory

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European Representative

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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

Jun Zhou
Place, date 2022.12.8

Wumin
Signature
QA manager: Wumin