



石家庄鸿锐集团

SHIJIAZHUANG HONGRAY GROUP

EU Declaration of Conformity

Factory

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European Representative

Caretechion GmbH
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Germany
DIMDI Code: DE/0000048026
Tel/Fax: 0211 3003 6618
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The undersigned **Shijiazhuang Hongray Group Co., Ltd.**, as manufacturer of:

Nitrile disposable gloves

Size	Blue 4.5g,29cm,9N	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:

1. 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;

Based on Annex VIII of MDR 2017/745, the medical device has been classified as belonging to I class.



The company has certified its own Quality and Management System in conformity to the norm EN

ISO 9001:2015(Certificate No. 011001732303 given on 18/08/2020 by TUV Rheinland).

2. the REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Type conformity based on B module EU Type Examination-Certificate Number: 2777/20660-01/E00-00. Issued by:**SATRA Technology Europe Limited**. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland. Notified Body: 2777.

In accordance with module C2 for PPE, the assessment procedure of evaluation of conformity has been carried out under the supervision of the notified body:**SATRA Technology Europe Limited**. Bracetown Business Park. Clonee. D15YN2P. Republic of Ireland.**Notified Body: 2777**

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

Jinzhou 2022.1.25

Place, date



Signature

QA manager:Wumin