

# EU Declaration of Conformity

*Manufacturer:*

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

*whose single Authorized Representative:*

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

We, the manufacturer, herewith declare that the products

**Disposable Nitrile Examination Glove**  
**With the size of XS, S, M, L, XL and XXL**  
**UMDNS-Code: 11882**

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

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



Applied harmonized standards: EN455-1:2020, EN455-2:2015, EN455-3:2015,  
EN455-4:2009, EN ISO 14971:2019, EN ISO 13485:2016.

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

Declare the conformity of their products by issuing the EU declaration of conformity referred to  
in Article 19 after drawing up the technical documentation set out in Annexes II and III.

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

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

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

Jinzhou China 2021-06-03

Place, date

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QD:    
Legally binding signature, Function

