

EU Declaration of Conformity

Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
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whose single Authorized Representative:

Caretechion GmbH
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We, the manufacturer, herewith declare that the products

Disposable Vinyl 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.

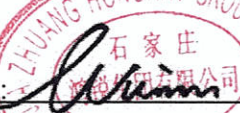
The above mentioned declaration of conformity is exclusively under the responsibility of

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

