

CE DECLARATION OF CONFORMITY

Manufacturer

Name: Shijiazhuang Hongray Group Co. Ltd.,

Address: South Tongda Road, East district, Jinzhou City, Hebei, 052260, China,

Declares that the MDD described hereafter

Products name and Model:

Disposable Nitrile Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC and Provisions of the Regulation (EU) 2017/745 which apply to them.

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex VIII.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC and Article 52 in MDR 2017/745.

The CE declaration of conformity is issued under the sole responsibility of Shijiazhuang Hongray Group Co. Ltd.

The products can be placed the following CE mark.

The CE mark is a stylized logo consisting of the letters 'C' and 'E' in a bold, sans-serif font, positioned to the left of the signature.

Signature: *Wu Min*

Date: March 03, 2020

Regulatory Authority