

EU Declaration of Conformity



石家庄鸿锐集团
SHIJIAZHUANG HONGRAY GROUP

European Representative

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Manufacturer

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052260

Hebei, China.

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The undersigned **Shijiazhuang Hongray Group Co., Ltd.**, as a manufacturer of:

Nitrile disposable gloves

SETINO CODE: N-1

PRODUCT CODE: NPF3001-3006

BASIC UDI-DI: 69487944

HONGRAY SRN: CN-MF-000024227

Declares that:

The product complies with the terms of EU Regulation 2017/745 (MDR) and conforms to the general safety and performance requirements (Annex I) as well as with the following applicable technical norms mentioned in the technical files:

EN455-1:2000, EN455-2:2015, EN455-3:2015, EN455-4:2009

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



The company has certified its own Quality and Management System in conformity to the norm EN ISO 9001:2015 (Certificate no. 011001732303 on 18/08/2020 by TUV Rheinland).

This EU Declaration of Conformity has been drafted on the basis of Annex IV of MDR 2017/745 under the sole responsibility of

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

Jinzhou China, 2022.02.15

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Place, Date

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Wu Min, QA manager

