



石家庄鸿锐集团
SHIJIAZHUANG HONGRAY GROUP

EU Declaration of Conformity



石家庄鸿锐集团
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Manufacturer:

Shijiazhuang Hongray Group Co., Ltd.
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Hebei, China.
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European Representative

Caretechion GmbH
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The undersigned **Shijiazhuang Hongray Group Co., Ltd.**, as manufacturer of

NITRILE EXAMINATION GLOVES, NON-STERILE, POWDER-FREE, BLACK
SETINO CODE: N-1

PROD. REF.: NPF4001-4005

BASIC UDI-DI: 69487944

Declares that

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

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

Based on Annex VIII of MDR 2017/745 UE, 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).

This EU declaration of conformity has been drafted based on annex IV of MDR 2017/745 under sole **Shijiazhuang Hongray Group Co., Ltd.**

South Tonda Rd., East Dist. Jinzhou, 052260 Hebei, China

Jinzhou, China, 2022.04.08

Place, date

Jinzhou Chen Wm. 48

Wu Min
QA manager.

