

# EU Declaration of Conformity



石家庄鸿锐集团  
SHIJIAZHUANG HONGRAY GROUP

## European Representative

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## Fabbricante

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

**Nitrile disposable gloves**  
**SETINO CODE: N-1**  
**PRODUCT CODE: NPF 2001-2005**

## 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 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 EU, 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 responsibility of

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

