



石家庄鸿锐集团
SHIJIAZHUANG HONGRAY GROUP

EU Declaration of Conformity

Manufacturer

Shijiazhuang Hongray Group Co., Ltd.
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The undersigned **Shijiazhuang Hongray Group Co., Ltd.**, as manufacturer,
Setino Hungary Kft as the importer and distributor of :

NITRILE EXAMINATION AND PROTECTIVE GLOVES (WITH SETINO ® TRADEMARK)

Intended Purpose: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery.

BASICUDI-DI: 69487944

Reference number	Product name
NPF4001	Nitrile Examination and Protective Gloves,black,XS
NPF4002	Nitrile Examination and Protective Gloves,black,S
NPF4003	Nitrile Examination and Protective Gloves,black,M
NPF4004	Nitrile Examination and Protective Gloves,black,L
NPF4005	Nitrile Examination and Protective Gloves,black,XL

Declares that

the product complies with the terms of EU 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 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 13/02/2023 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 Tonda Rd., East Dist. Jinzhou, 052260 Hebei, China

shijiazhuang 2023.8.24
Place and date

Wu Min
QA manager:Wu Min

