



石家庄鸿锐集团
SHIJIAZHUANG HONGRAY GROUP

EU Declaration of Conformity

Manufacturer

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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.

PRODUCT CODE: NPF3001-3006

BASICUDI-DI: 69487944

Reference number	Product name
NPF3001	Nitrile Examination and Protective Gloves, disposable, powder free, blue, XS
NPF3002	Nitrile Examination and Protective Gloves, disposable, powder free, blue, S
NPF3003	Nitrile Examination and Protective Gloves, disposable, powder free, blue, M
NPF3004	Nitrile Examination and Protective Gloves, disposable, powder free, blue, L
NPF3005	Nitrile Examination and Protective Gloves, disposable, powder free, blue, XL
NPF3006	Nitrile Examination and Protective Gloves, disposable, powder free, blue, XXL

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 13485:2016 (Certificate no. SX 2174809-1 given on 06/04/2023 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



QA Manager: Wu Min (Signature)

shijiazhuang 2023.8.24.
Place, date