



石家庄鸿锐集团  
SHIJIAZHUANG HONGRAY GROUP

## EU Declaration of Conformity

### Manufacturer

Shijiazhuang Hongray Group Co., Ltd.  
South Tongda Rd., East Dist. Jinzhou, 052260  
Hebei, China.  
Tel: +86-311-83610904  
Fax: +86-311-83610904  
SRN: CN-MF-000024227

### European Representative

Caretechion GmbH  
Niederrheinstr.71, 40474 Düsseldorf, Germany  
DIMDI Code: DE/0000048026  
Tel/Fax: 0211 30033 6681  
Email: info@caretechion.de  
SRN: DE-AR-000005946

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:** NPF5001-5006

**BASICUDI-DI:** 9487944

Reference number	Product name
NPF5001	Nitrile Examination and Protective Gloves, disposable, powder free, white, XS
NPF5002	Nitrile Examination and Protective Gloves, disposable, powder free, white, S
NPF5003	Nitrile Examination and Protective Gloves, disposable, powder free, white, M
NPF5004	Nitrile Examination and Protective Gloves, disposable, powder free, white, L
NPF5005	Nitrile Examination and Protective Gloves, disposable, powder free, white, XL
NPF5006	Nitrile Examination and Protective Gloves, disposable, powder free, white, 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**

*Shijiazhuang 2022.12.19*

Place, date

*Wu Min*

QA Manager: Wu Min (Signature)

