

## EU DECLARATION OF CONFORMITY

Manufacturer

*Name:* Anhui Intco Medical Products  
Co.,Ltd.

*Address:* No. 6, Haitang South Road, Suixi  
Wuhu Modern Industrial Park, Suixi  
County, Huaibei City, Anhui Province

Authorized Representative

*Name:* Lotus NL B.V.

*Address:* Koningin Julianaplein 10, le Verd,  
2595AA, The Hague, Netherlands

Declares that the MDR described hereafter

*Product name and model:*

**Disposable Nitrile Exam Gloves**

**EMDN code: T01020204**

**Model:** XS/S/M/L/XL/XXL

**Product Code:** See the following annex I

**Basic UDI-DI:** 697306977NitrileFR

**SRN:** CN-MF-000002356

This declaration of conformity is issued under the sole responsibility of the manufacturer:

**Anhui Intco Medical Products Co.,Ltd.**

Conformity Assessment Route: Annex II and Annex III according to EU 2017/745.

Applicable Standard:

EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016

EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-11:2017

Meet the provisions of the Council Regulation EU 2017/745 and Annex I which apply to them,

The medical device has been assigned to Class I, based on rule 1 & rule 5 of Annex VIII

Chapter III of the Regulation EU 2017/745 MDR. It bears the mark



We agree to develop, implement and maintain a documented post-production monitoring process



**Annex 1 product code**

| Color  | Product Code                      |
|--------|-----------------------------------|
| Blue   | NGV/B/H/PEM10013-NGV/B/H/PEM10018 |
|        | NGV/B/H/PEM20013-NGV/B/H/PEM20018 |
|        | SNV/B/H/PE10013-SNV/B/H/PE10018   |
|        | SNV/B/H/PE20013-SNV/B/H/PE20018   |
| White  | NGV/B/H/PEM10023-NGV/B/H/PEM10028 |
|        | NGV/B/H/PEM20023-NGV/B/H/PEM20028 |
|        | SNV/B/H/PE10023-SNV/B/H/PE10028   |
|        | SNV/B/H/PE20023-SNV/B/H/PE20028   |
| Voilet | NGV/B/H/PEM10033-NGV/B/H/PEM10038 |
|        | NGV/B/H/PEM20033-NGV/B/H/PEM20038 |
|        | SNV/B/H/PE10033-SNV/B/H/PE10038   |
|        | SNV/B/H/PE20033-SNV/B/H/PE20038   |
| Black  | NGV/B/H/PEM10043-NGV/B/H/PEM10048 |
|        | NGV/B/H/PEM20043-NGV/B/H/PEM20048 |
|        | SNV/B/H/PE10043-SNV/B/H/PE10048   |
|        | SNV/B/H/PE20043-SNV/B/H/PE20048   |
| Pink   | NGV/B/H/PEM10053-NGV/B/H/PEM10058 |
|        | NGV/B/H/PEM20053-NGV/B/H/PEM20058 |

Anhui 2021-10-30

Place , date



Quality Manager

Legally binding signature, Function

