INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/2

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

CE

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