Document Number :INTCO-CE-DC-NBR-001 Version:A/3

EU DECLARATION OF CONFORMITY

Manufacturer

Name:Anhui Imtco Medical Products Co.,Ltd.

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

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 I and Annex II according to EU 2017/745.

Applicable Standard:

ISO 13485:2016; EN ISO14971:2019; EN ISO 20417:2021; EN ISO 15223-1:2021

EN 455-1:2020+A2:2024; EN 455-2:2024; EN 455-3:2023; EN 455-4:2009;

ISO 10993-1:2018; ISO 10993-10:2021; ISO 10993-11:2017; ISO 10993-23:2021

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 VII Chapter II 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
	SNV/B/H/PE10053-SNV/B/H/PE10058
	SNV/B/H/PE20053-SNV/B/H/PE20058
Yellow	NGV/B/H/PEM10063-NGV/B/H/PEM10068
	NGV/B/H/PEM20063-NGV/B/H/PEM20068
	SNV/B/H/PE10063-SNV/B/H/PE10068
	SNV/B/H/PE20063-SNV/B/H/PE20068
Red	NGV/B/H/PEM10073-NGV/B/H/PEM10078
	NGV/B/H/PEM20073-NGV/B/H/PEM20078
	SNV/B/H/PE10073-SNV/B/H/PE10078
	SNV/B/H/PE20073-SNV/B/H/PE20078
Green	NGV/B/H/PEM10083-NGV/B/H/PEM10088
	NGV/B/H/PEM20083-NGV/B/H/PEM20088
	SNV/B/H/PE10083-SNV/B/H/PE10088
	SNV/B/H/PE20083-SNV/B/H/PE20088
	NGV/B/H/PEM10093-NGV/B/H/PEM10098

Orange	NGV/B/H/PEM20093-NGV/B/H/PEM20098
	SNV/B/H/PE10093-SNV/B/H/PE10098 SNV/B/H/PE20093-SNV/B/H/PE20098

Anhui 2025-09-26
Place,date

Quality Manager
Legally binding signature,Function