

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 455-1:2000; 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 2021-04-16

Place , date

Quality Manager

 Legally binding signature, Function



安徽英科医疗制品有限公司
Anhui Intco Medical Products Co., Ltd.

文件编号 Doc No.

INTCO-PPE-NBR

版本 Ver.

A0

EU Declaration of Conformity

1. PPE: Disposable Nitrile Gloves

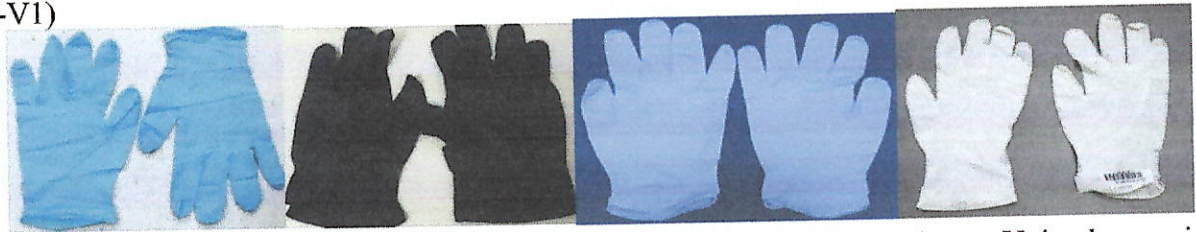
Glove sizes available: XS, S, M, L, XL, XXL (6, 7, 8, 9, 10, 11)

2. Manufacturer Name: Anhui Intco Medical Products Co., Ltd.

Address: (Haitang Road West and Yinhua Road North) Suixi Wuhu Modern Industrial Park, Suixi Town, Huaibei City, Anhui, China

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Anhui Intco Medical Products Co., Ltd.

4. Object of the declaration: Disposable Nitrile Gloves (Blue-NGPF; Black -BNPF; White-WNPF; Violet -NGPF-V1)



5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: Regulation (EU)2016/425.

6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-2:2014, EN ISO 374-5:2016.

7. The notified body SATRA Technology Europe Ltd (Number: 2777) performed the EU type-examination (Module B) and issued the EU type-examination certificate.

8. The PPE is subject to the conformity assessment procedure Module C2 under surveillance of the notified body : SATRA Technology (Number: 2777),

Address: Bracetown Business Park Clonee, D15 YN2P, Ireland.

Signed for and on behalf of: Anhui Intco Medical Products Co., Ltd.

签名 Signature 崔忠强

职位 Position Quality Manager

日期 Date 16 July 2020

