Issued to:

Anhui Intco Medical Products Co., Ltd
No. 6, Haitang South Road
Suixi Wuhu Modern Industrial Park
Suixi County
Huaibei City
Anhui Province
China

Notified Body: 2777

SATRA customer number: P21130

EU Type-Examination Certificate

Certificate number: 2777/22223-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product reference: NGX/S/TEXXXXX

Description: Disposable Nitrile Gloves, Non-sterile

Blue	Green
NGX/S/TE10014-NGX/S/TE10018	NGX/S/TE10084- NGX/S/TE10088
NGX/S/TE20014-NGX/S/TE20018	NGX/S/TE20084- NGX/S/TE20088
NGX/S/TE10F14-NGX/S/TE10F18	NGX/S/TE10F84- NGX/S/TE10F88
NGX/S/TE20F14-NGX/S/TE20F18	NGX/S/TE20F84- NGX/S/TE20F88
NGX/S/TE10P14-NGX/S/TE10P18	NGX/S/TE10P84- NGX/S/TE10P88
NGX/S/TE20P14-NGX/S/TE20P18	NGX/S/TE20P84- NGX/S/TE20P88
Violet	**Black**
NGX/S/TE10034- NGX/S/TE10038	NGX/S/TE10044- NGX/S/TE10048
NGX/S/TE20034- NGX/S/TE20038	NGX/S/TE20044- NGX/S/TE20048
NGX/S/TE10F34- NGX/S/TE10F38	NGX/S/TE10F44- NGX/S/TE10F48
NGX/S/TE20F34- NGX/S/TE20F38	NGX/S/TE20F44- NGX/S/TE20F48
NGX/S/TE10P34- NGX/S/TE10P38	NGX/S/TE10P44- NGX/S/TE10P48
NGX/S/TE20P34- NGX/S/TE20P38	NGX/S/TE20P44- NGX/S/TE20P48

Sizes: 7-11(S-XXL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
(K) Sodium hydroxide 40%	6	-30.1
(P) Hydrogen peroxide 30%	3	43.1
(T) Formaldehyde 37%	6	-17.5
(O) Ammonium hydroxide 25%	2	-3.58

EN ISO 374-5:2016	**Level**
Protection against Bacterial and Fungi	Pass
Protection against Viruses	Pass

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Date: 2025.06.06 21:29:22 EEST
Reason: MoldSign Signature
Location: Moldova
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Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0316811/2129, CHM0317791/2132/EN/A, CHM0317783/2132/LC, CHT0329910/2216, CHT0335653/2232, CHT0335234/2231, CHT0333975/2228
SGS: QDHL2206007432HM, QDHL2206008535HM
TUV: 7191266610-EEC21-WBH-CR2

Signed on behalf of SATRA: Geoff Graham

Date first issued: 29/08/2022
Date of issue: 29/08/2022
Expiry date: 29/08/2027

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

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