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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd.

Main Site: Qiwang Road No.9888, Naoshan Industrial Park, Qingzhou City, Shandong Province, 262500, P. R. China

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Manufacture of non-sterile NBR (nitrile butadiene rubber), PVC (poly vinyl chloride), and latex medical examination gloves. Design and manufacture of non-sterile disposable ECG electrodes, medical face masks, sterile latex surgical gloves, latex exam gloves, and nitrile exam gloves.

Digitally signed by Cojocaru Vera
Date: 2026.05.07 07:43:24 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Certificate Number:
0086238-03

Initial Certification Date:
28 April 2014

Date of Certification Decision:
13 December 2024

Issuing Date:
13 December 2024

Valid Until:
31 December 2027

ISO 13485:2016 CERTIFICATION TM
intertek

SCC Accredited CB-MS OCSM Accrédité CCN TM
The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA, Inc. dba Intertek
4700 Broadmoor SE, Suite 200
Kentwood, Michigan 49512, United States

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/5

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Authorized Representative

Name: **Lotus NL B.V.**

Address: **Koningin Julianaplein 10, 1e 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: NGV/B/H/PEM 10013-10018, NGV/B/H/PEM 10023-10028, NGV/B/H/PEM 10033-10038, NGV/B/H/PEM 10043-10048, NGV/B/H/PEM 10053-10058.

Basic UDI-DI: 697024575Nitrile7G

SRN: CN-MF-000002100

This Declaration of Conformity is issued under the sole responsibility of the manufacturer: Shandong 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.

Rick cheng

Shandong 2021-04-12 Rick Cheng/Quality Manager

Place , date *Legally binding signature, Function*

Issued to:

Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou
Shandong
262506
China

Notified Body: 2777

SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/17447-02/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:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

NGV/B/H/P/XE100
NGV/B/H/P/XE200
SNV/B/H/PE100
SNV/B/H/PE200

Description:

Disposable Nitrile Gloves/ SYNGUARD® Nitrile Exam Gloves

Blue	Black
NGV/B/H/P/XE100 13-18	NGV/B/H/P/XE100 43-48
NGV/B/H/P/XE200 13-18	NGV/B/H/P/XE200 43-48
SNV/B/H/PE100 13-18	SNV/B/H/PE100 43-48
SNV/B/H/PE200 13-18	SNV/B/H/PE200 43-48

White	Violet
NGV/B/H/P/XE100 23-28	NGV/B/H/P/XE100 33-38
NGV/B/H/P/XE200 23-28	NGV/B/H/P/XE200 33-88
SNV/B/H/PE100 23-28	SNV/B/H/PE100 33-38
SNV/B/H/PE200 23-28	SNV/B/H/PE200 33-38

Sizes:
6-11(XS-XXL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
(K) Sodium hydroxide 40%	6	-11.5
(P) Hydrogen peroxide 30%	2	-9.5
(T) Formaldehyde 37%	3	7.4

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

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: CHT0291374/1944, CHM0291937/1946/JH, CHT0301241/2033
SGS: CH:TX:9420026599-1, CH:TX:9420026316-1, CH:TX:9420020333, CH:TX:9420029243
CTC: S200908976_2
TUV: 721655656

Signed on behalf of SATRA:

Geoff Graham

Date first issued: 15/07/2021
Date of issue: 20/07/2021
Expiry date: 15/07/2026

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.