## NOTARIAL CERTIFICATE

To All to whom these presents shall come

I, CHING YIN KAY MASON, Notary Public, duly admitted, authorized and sworn, practising in Hong Kong, Special Administrative Region of the People's Republic of China, DO HEREBY CERTIFY that to the best of my knowledge and belief the annexed documents are copies of the documents provided by Shandong Intco Medical Products Co., Ltd.; namely:-

- 1. Certificate of Registration (Certificate Number: 0086238-02) of **Shandong Intco Medical Products Co., Ltd.** issued by Intertek Testing Services NA Ltd. dated 31 December 2021.
- 2. People's Republic of China Certificate for Exportation of Medical Products of **Shandong Intco Medical Products Co., Ltd.** issued by Shandong Drug Administration dated 12 September 2023; and
- 3. EU Declaration of Conformity (Document Number: INTCO-CE-DC-NBR-002) of **Shandong Intco Medical Products Co., Ltd.** dated 1 June 2023.

In Faith and Testimony whereof I the said Notary have subscribed my name and affixed my seal of office at the Hong Kong Special Administrative Region aforesaid this 8th day of December in the Year Two Thousand and Twenty-three.

CHING YIN KAY MASON

Masmly

**NOTARY PUBLIC** 

HONG KONG S.A.R.

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. To verify the issuance of this Apostille, see

"https://www.judiciary.hk/en/court\_services\_facilities/apostille\_verification.html"

此獨文件加養儀就公共文件上簽署的真確性、簽署人的身分及,如適用的話,文件上 的蓋塞蓋印予以證明。此項文件加養並不就文件的內容作出證明。就發出此文件加簽

|    | 之查證,見   |  |  |     |                              | es/apostille_verification.html" |  |
|----|---|--|--|-----|------------------------------|---------------------------------|--|
|    |   | (Convent   | APOSTII<br>ion de La Haye                            |     |                              | bre 1961)                       |  |
| 1. | 1. Country:<br>國家/地區                          |  | Hong Kong, China<br>中國香港                             |     |                              |                                 |  |
|    | This public doo<br>此公共文件                      | This public document<br>此公共文件                    |  |     |                              |                                 |  |
| 2. | has been signed by<br>簽署人為                    |  | CHING Yin Kay Mason                                  |     |                              |                                 |  |
| 3. | acting in the ca<br>其行事的身分                    | Notary Public<br>公證人                             |  |     |                              |                                 |  |
| 4. | bears the seal / stamp of CHING Yin Kay Mason |  |  |     |                              |                                 |  |
|    | 蓋有的蓋章/蓋印                                      |  |  |     |                              |                                 |  |
|    |   |  | Certifie<br>加簽證                                      |     |                              |                                 |  |
| 5. | at<br>在                                       | High Cou<br>高等法院                                 | igh Court 6. the 11 DEC 2023<br>等法院 於 2023 年 12 月 11 |     | 11 DEC 2023<br>2023年 12月 11日 |                                 |  |
| 7. | by<br>由                                       | Simon KWANG Registrar, High Court  鄭卓宏 高等法院司法常務官 |  |     |                              |                                 |  |
| 8. | No<br>編號                                      | 135908 / 2023                                    |  |     |                              |                                 |  |
| 9. | Seal / stamp:<br>蓋章/蓋印                        | A. S.        | 去院与  | 10. | Signat<br>簽署                 | ure:                            |  |

Reference Code 参考編號:1189FD85

## 中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 鲁潍药监械出 20230010 号 Certificate NO.:

产品名称: 见附件 Product(s):See attachment

规格型号: 见附件

Model: See attachment

产品注册或备案凭证号: 见附件 Registration certificate(s): See attachment

生产企业: 山东英科医疗制品有限公司 Manufacturer: SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

生产企业住所: 青州市峱山工业园齐王路 9888 号 Address of manufacturer:No.9888 Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, 262500, China

生产许可或备案凭证号: 鲁潍食药监械生产备 20160008 号 Manufacturing License(s):

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2025年9月11日 This certification valid until:11/09/2025

备注: (1) Remark: (1)



## 中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 医疗器械产品出口销售证明 CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

附件 Attachment

| 证书编号: | 鲁潍药监 | 戒出 20 | 02300 | )10号 |
|-------|------|-------|-------|------|
|-------|------|-------|-------|------|

| 业节狮 | 号:鲁潍约监概出202                                   |   |                   |  |  |
|-----|---|---|-------------------|--|--|
| NO. | 产品名称 Products                                 | 专用章 规格型号 Model  | 注册或备案号            |  |  |
|     |   | (2)   | Registration      |  |  |
|     |   |   | certificate(s)    |  |  |
|     |   | 无粉麻面、有粉麻面、无粉光面、有  | 鲁 潍 械 备 20180029号 |  |  |
| 1   | 医用乳胶检查手套                                      | 粉光面; XXL、XL、L、M、S、XS  | 20100029 7        |  |  |
|     | Latex<br>examination<br>gloves                | Powder free and textured,   | 品监察               |  |  |
|     |   | powdered and textured, powder   | A                 |  |  |
|     |   | free and smooth surface,  |                   |  |  |
|     |   | powdered and smooth surface ;   | 一品出口角香            |  |  |
|     | (A) (B) (B) (B) (B) (B) (B)                   | Size: XXL, XL, L, M, S, XS  | (2)               |  |  |
| 2   | 医用丁腈检查手套,<br>Nitrile<br>examination<br>gloves | 无粉指麻、有粉指麻; XXL、XL、L、M、S、XS Powder free and fingertip textured, powdered and fingertip textured; Size: XXL、XL、L、M、S、XS | 鲁 潍 械 备 20180030号 |  |  |
| 3   | 医用 PVC 检查手套<br>Vinyl<br>examination<br>gloves | 无粉光面、有粉光面; XXL、XL,L,M,S,XS Powder free and non-textured, powdered and non-textured; Size: XXL、XL、L、M、S、XS             | 鲁 潍 械 备 20180031号 |  |  |
| 4   | 医用检查手套<br>Medical<br>Examination<br>Gloves    | 无粉光面、有粉光面; XL、L、M、S、XS powder free and non-textured, powdered and non-textured; Size: XL、L、M、S、XS                     | 鲁 潍 械 备 20200028号 |  |  |



Document Number : INTCO-CE-DC-NBR-002

Version: A/0

## EU DECLARATION OF CONFORMITY

Manufacturer

Name: Shandong Intco Medical Products

Co., Ltd.

Address: Qiwang Road NO.9888, Naoshan

Industrial Park, Qingzhou, Shandong, China

Declares that the MDR described hereafter

Product name and model:

Authorized Representative

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd,

2595AA, The Hague, Netherlands

Disposable Nitrile Exam Gloves / SYNGUARD® Nitrile Exam Gloves EMDN code: T01020204

Model: XS /S /M /L /XL/XXL

Product Code: NGV/B/H/PEM; SNV/B/H/PE (Please refer to the attachment for more

details.).

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. The declaration is valid for 3 years.

Shandong 2023/06/01-2026/06/01

Place, date



|        | Size             |                  |                  |                  |                  |                                  |  |  |
|--------|------------------|------------------|------------------|------------------|------------------|----------------------------------|--|--|
| color  | XS               | S                | M                | L                | XL               | XXL                              |  |  |
|        | NGV/B/H/PEM10013 | NGV/B/H/PEM10014 | NGV/B/H/PEM10015 | NGV/B/H/PEM10016 | NGV/B/H/PEM10017 | NGV/B/H/PEM100                   |  |  |
|        | NGV/B/H/PEM20013 | NGV/B/H/PEM20014 | NGV/B/H/PEM20015 | NGV/B/H/PEM20016 | NGV/B/H/PEM20017 | NGV/B/H/PEM200                   |  |  |
| Blue   | SNV/B/H/PE10013  | SNV/B/H/PE10014  | SNV/B/H/PE10015  | SNV/B/H/PE10016  | SNV/B/H/PE10017  | SNV/B/H/PE1001                   |  |  |
|        | SNV/B/H/PE20013  | SNV/B/H/PE20014  | SNV/B/H/PE20015  | SNV/B/H/PE20016  | SNV/B/H/PE20017  | SNV/B/H/PE2001                   |  |  |
|        | NGV/B/H/PEM10023 | NGV/B/H/PEM10024 | NGV/B/H/PEM10025 | NGV/B/H/PEM10026 | NGV/B/H/PEM10027 | NGV/B/H/PEM100                   |  |  |
| White  | NGV/B/H/PEM20023 | NGV/B/H/PEM20024 | NGV/B/H/PEM20025 | NGV/B/H/PEM20026 | NGV/B/H/PEM20027 | NGV/B/H/PEM200                   |  |  |
| wnite  | SNV/B/H/PE10023  | SNV/B/H/PE10024  | SNV/B/H/PE10025  | SNV/B/H/PE10026  | SNV/B/H/PE10027  | SNV/B/H/PE1002                   |  |  |
|        | SNV/B/H/PE20023  | SNV/B/H/PE20024  | SNV/B/H/PE20025  | SNV/B/H/PE20026  | SNV/B/H/PE20027  | SNV/B/H/PE2002                   |  |  |
|        | NGV/B/H/PEM10033 | NGV/B/H/PEM10034 | NGV/B/H/PEM10035 | NGV/B/H/PEM10036 | NGV/B/H/PEM10037 | NGV/B/H/PEM100                   |  |  |
| violet | NGV/B/H/PEM20033 | NGV/B/H/PEM20034 | NGV/B/H/PEM20035 | NGV/B/H/PEM20036 | NGV/B/H/PEM20037 | NGV/B/H/PEM200                   |  |  |
| 10101  | SNV/B/H/PE10033  | SNV/B/H/PE10034  | SNV/B/H/PE10035  | SNV/B/H/PE10036  | SNV/B/H/PE10037  | SNV/B/H/PE1003                   |  |  |
|        | SNV/B/H/PE20033  | SNV/B/H/PE20034  | SNV/B/H/PE20035  | SNV/B/H/PE20036  | SNV/B/H/PE20037  | SNV/B/H/PE2003                   |  |  |
|        | NGV/B/H/PEM10043 | NGV/B/H/PEM10044 | NGV/B/H/PEM10045 | NGV/B/H/PEM10046 | NGV/B/H/PEM10047 | NGV/B/H/PEM100                   |  |  |
| Black  | NGV/B/H/PEM20043 | NGV/B/H/PEM20044 | NGV/B/H/PEM20045 | NGV/B/H/PEM20046 | NGV/B/H/PEM20047 | NGV/B/H/PEM200                   |  |  |
| DIACK  | SNV/B/H/PE10043  | SNV/B/H/PE10044  | SNV/B/H/PE10045  | SNV/B/H/PE10046  | SNV/B/H/PE10047  |                                  |  |  |
|        | SNV/B/H/PE20043  | SNV/B/H/PE20044  | SNV/B/H/PE20045  | SNV/B/H/PE20046  | SNV/B/H/PE20047  | SNV/B/H/PE1004<br>SNV/B/H/PE2004 |  |  |