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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) and PVC (Poly Vinyl Chloride) medical examination gloves.

Certificate Number:
0086238-01

Initial Certification Date:
28 April 2014

Date of Certification Decision:
9 January 2021

Issuing Date:
9 January 2021

Valid Until:
31 December 2021

ISO 13485:2016 CERTIFICATION™
Intertek

SCC Accredited CB-MS
OCSM Accrédité CCN™

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Shandong Intco Medical Products Co., Ltd

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

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

ISO 9001:2015

The management system is applicable to:

Manufacturing of disposable non sterile NBR (Nitrile Butadiene Rubber) and PVC (Poly Vinyl Chloride) gloves and disposable face masks （Non-medical）.

(Organization was certified by another Certification Body before 2019/01/03)

Unified Social Credit Identifier:
91370781561439654L
Certificate Number:
111812005
Initial Certification Date:
27 January 2013
Date of Certification Decision:
23 December 2020
Certified by Intertek since:
03 January 2019
Issuing Date:
23 December 2020
Valid Until:
27 January 2022

ISO 9001:2015 CERTIFICATION™
Intertek
UKAS MANAGEMENT SYSTEMS
014

Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

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The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

Issued to:

Shandong IntcoMedical 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: 2777/11804-02/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:	**Description:**
NGV/B/H/PEM100	Five fingered disposable nitrile non-sterile gloves.
Blue NGV/B/H/PEM100 13-18	
White NGV/B/H/PEM100 23-28	
Violet NGV/B/H/PEM100 33-38	
Black NGV/B/H/PEM100 43-48	

Sizes:
XS/6
S/7
M/8
L/9
XL/10
XXL/11

Classification:

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

EN ISO 374-5: 2016	
Protection against Bacteria 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: CHT0301241/2033, CHM0291937/1946/JH, CHT0291374/1944
SGS: CH:TX:9420026599-1, CH:TX:9420026316-1, CH:TX:9420029243, CH: TX:9420020333
CTC: S200908976_2
TUV: 721655656

Signed on behalf of SATRA: Daisy He Daisy He Quincey Brown

Date first issued: 30/01/2019
Date of issue: 25/09/2020

Expiry date: 30/01/2024