Disposable Nitrile Exam Gloves

Features

- No latex protein to cause allergy
- Excellent softness and wearing fitness
- Undifferentiated shelf life as normal gloves
- Well suitable for high cleanliness industry like electronic, food service, etc

Quality Standards

- Complies with EN 455 and EN 374
- Complies with ASTM D6319 (USA Related Product)
- Complies with ASTM F1671
- FDA 510(K) available
- Approved to use with Chemotherapy Drugs

Applications

- Medical Purpose / Examination
- Industrial purpose / PPE
- Laboratory
- Healthcare and nursing
- General housekeeping
- IT Industry

FDA DIN EN 455 CE LATEX ISO374-5 Virus AQL 1.5

SKU	Size	Color	Package	Box Size	Carton Dimension
NGBEM1001*	XS-XL	Blue	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm
NGBEM1002*	XS-XL	White	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm
NGBEM1003*	XS-XL	Violet	100pcs/box,10boxes/ctn	230*125*60mm	315*258*245mm

※ The last "*" means Size:3-XS 4-S 5-M 6-L 7-XL.

INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/1

EU DECLARATION OF CONFORMITY

Manufacturer

Name: **Shandong Intco Medical Products Co., Ltd.**
Address: **Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China**

Authorized Representative

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

Address: **Koningin Julianaplein 10, le Verd, 2595AA， The Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile（NBR）Gloves

UMDNS code：11882

UDI-DI: （**XS, S, M, L, XL, XXL**）

Blue Gloves： 6970245756014 / 6970245756021 / 6970245756038 / 6970245756045 / 6970245756052 / 6970245756069

White Gloves： 6970245756410 / 6970245756427 / 6970245756434 / 6970245756441 / 6970245756458 / 6970245756465

Black Gloves： 6970245756519 / 6970245756526 / 6970245756533 / 6970245756540 / 6970245756557 / 6970245756564

Violet Gloves： 6970245756311 / 6970245756328 / 6970245756335 / 6970245756342 / 6970245756359/ 6970245756366

Meet the provisions of the Council Regulation EU 2017/745 which apply to them.

The medical device has been assigned to class **I** according to Annex *VIII* of the Regulation EU 2017/745. It bears the mark CE

CONFORMITY ASSESSMENT ROUTE: *EU 2017/745, Annex I & VII*

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shandong Intco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park. Qingzhou, Shandong, China

Shandong 2019-05-06
Place , date

Chi Yongtao Plant manager
Legally binding signature, Function

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: 2777/11804-01/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:
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:

697024575

Blue 697024575 601-605

Violet 697024575 631-635

White 697024575 641-645

Black 697024575 651-655

Description:

Five fingered disposable nitrile non-sterile gloves.

Sizes:

6/XS, 6.5/S, 7/M, 8/L, 9/XL

Classification:

EN ISO 374-1:2016+A1:2018 /Type B	**Level**	**EN 374-4: 2013**
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 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0278438/1848
SGS: QDHL1806013113OT, CH:TX:6420074520, CH:TX: 9420020333, CH:TX: 9420029243 CH:TX: 9420026599-1, CH:TX: 9420014953-1, CH:TX: 9420026316-1, CH:TX: 9420614959
TUV: 721642857-2

Signed on behalf of SATRA: Tara Saunders Geoff Graham

Date first issued: 30/01/2019
Date of issue: 30/01/2019

Expiry date: 30/01/2024

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.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product 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 manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. 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 government.
8. 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.
9. SATRA Technology 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 Regulation 2016/425.

Test Report No. 7191205302-EEC19-WBH
dated 01 Mar 2019

PSB Singapore

Add value.
Inspire trust.

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Disposable Nitrile Glove submitted by
Shandong Intco Medical Products Co., Ltd. on 18 Feb 2019.

TESTED FOR:

Shandong Intco Medical Products Co., Ltd
No. 9888 Qiwang Road
Naoshan Industry Park, Qingzhou, Shandong, China

TEST DATE:

25 Feb 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Glove	Blue	/	M	217	Shandong Intco Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

Phone : +65-6885 1333
Fax : +65-6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Glove, Size M

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	0	Passed

REMARKS:

1. The manufacturing lot no. was not provided by the client.

Yeo Poh Kwang
Higher Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo : Disposable Nitrile Glove, Size M

PSB Singapore

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.

2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.

3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.

4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.

5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
NO.9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

The following sample(s) was/were submitted and identified by the client as:

Sample Description	: METRO/MAKRO PROFESSIONAL NITRILE GLOVES, NON-POWDERED, BLUE
Sample Receiving Date	: SEP.12,2019
Testing Period	: SEP.12,2019 TO SEP.25,2019
Test Performed	: SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested	: EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES
Test Result(s)	: PLEASE REFER TO THE FOLLOWING PAGE(S)
Conclusion	: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS-CSTC Standards
Technical Services (Qingdao)
Co., Ltd.

QDHL1909015461OT

Zhou Xinkuan, SK
Lab Manager

SGS Center, No. 143, Zhuzhou Road, Laoshan District, Qingdao, China 266101
t (86-532) 68999888 f (86-532) 80991955
www.sgsgroup.com.cn
e sgs.china@sgs.com

Test Conducted:

EN 455-2-2015 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
The type of gloves	:	examination/procedure gloves c)
Manufacturing batch code	:	/
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
5	Strength	---	---
5.2	Force at break	Pass	# 1
5.3	Force at break after challenge testing	Pass	# 1

Notes : #1 See result 1

Test Result:

1. Strength

Sample Quantity: 13pcs

Size	M												
Force at break(N)	7.8	8.5	8.0	9.0	9.4	8.9	6.8	7.1	8.2	8.9	8.3	8.6	8.4
Force at break after challenge testing(N)	7.8	7.6	8.3	7.6	6.5	6.1	8.4	7.4	6.8	6.8	8.5	7.2	6.0

Median value:

Force at break during shelf life (N): 8.4

Force at break after challenge testing (N): 7.4

Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6

a) Requirements for all surgical gloves.
b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene)..
c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).

Sample Photo:

Received sample

SGS authenticate the photo on original report only

End of Report

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Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 1 OF 2
Date of Report : Dec. 25, 2018

Shandong Intco Medical Products Co., Ltd.
No.9888, Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China

Product Name	Disposable Nitrile Glove (QDHL1811025521OT)
Date of Sample Received	Dec. 10, 2018
Date of Testing	Dec. 10, 2018~Dec. 25, 2018
Remark	The information mentioned in the above section is provided by Client(Exclude Date of Sample Received and Date of Testing)

==========

The laboratory tests according to the test requests and samples provided by client, and the results are as follows:

Test Request : Aqueous Extractable Protein

Test Method : Refer to BS EN 455-3:2015 Medical gloves for single use — Part 3 : Requirements and testing for biological evaluation

Test Result : Please see attached pages

----- 1 -----

The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

Signed for and on behalf of
SGS Taiwan Ltd.

Material and Engineering Laboratory-Kaohsiung

Test Report

Report No. : KV-18-11251
Page No. : 2 OF 2
Date of Report : Dec. 25, 2018

Test Equipment :

Name	Brand	Model
UV-VISIBLE Spectrophotometer	SHIMADZU	UV-1700

Lab. Environmental Conditions:

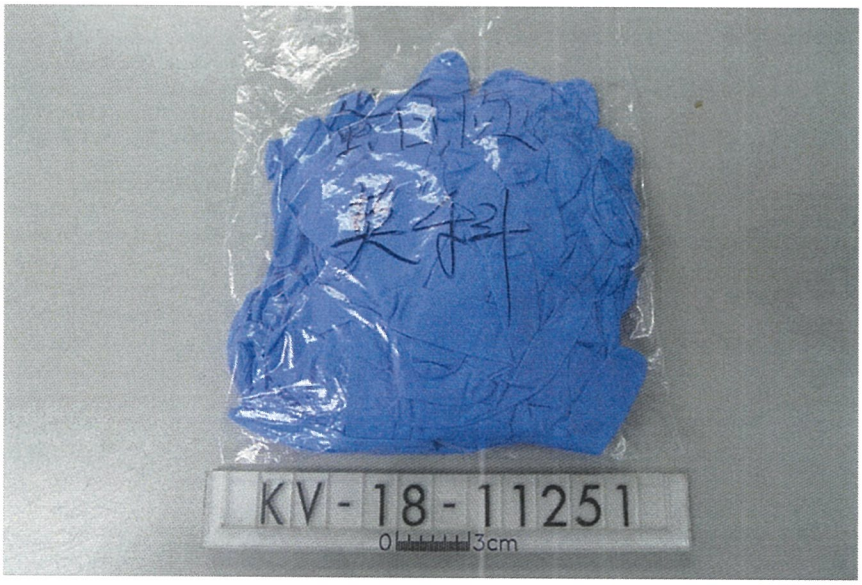
Ambient Temperature : (25 ± 2) ℃
Relative humidity : (50 ± 10) %

Test Result :

INSPECTION ITEM	TEST RESULT
Aqueous Extractable Protein (ppm)	n.d.

Note: 1. n.d. = not detected.
2. MDL (METHOD DETECTION LIMIT):0.2ppm.

Sample Photo :



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The required specification(s) offered in this test report is/are for reference only.
The conformity judgment is at the Applicant's final verdict.

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