INTCO
英科医疗

Document Number ：INTCO-CE-DC-NBR-001 Version: A/4

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 Hague，Netherlands**

Declares that the MDR described hereafter

Product name and model:

Disposable Nitrile（NBR）Gloves

UMDNS code：11882

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

UDI-DI:

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 of Annex VIII Chapter III of the Regulation EU 2017/745 MDR. It bears the mark

CE

This Declaration of conformity is valid for five years: 7 / May / 2020 to 6 / May / 2025. If there is a change in the declaration information, this declaration is invalid.

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 2020-05-07
Place , date

Cui Zhongqiang Quality Manager
Legally binding signature, Function

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*

intertek
Total Quality. Assured.

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

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

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.

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.

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

Test Report No. 7191255592-EEC21-WBH
dated 31 Mar 2021

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 Examination Gloves submitted by
Shandong Intco Medical Products Co., Ltd. on 10 Mar 2021

TESTED FOR:

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

TEST DATE:

12 Mar 2021 to 31 Mar 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Examination Gloves	Nil	Blue	Nil	S	15	Shandong Intco Medical Products Co., Ltd.
2				Nil	M	32	
3				Nil	L	15	
4				Nil	XL	15	

METHOD OF TEST:

EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 4 Dimensions
-Clause 5 Strength

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

Phone : +65-6778 7777
E-mail: info.sg@tuvsud.com
https://www.tuvsud.com/sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Examination Gloves

Table: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	S	≥ 240	13	248	Passed
		M		13	243	Passed
		L		13	248	Passed
		XL		13	250	Passed
	b) Width (mm)	S	80 ± 10	13	83	Passed
		M	95 ± 10	13	98	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	110	Passed
5	Strength a) Force at break (N)	M	For nitrile examination gloves: ≥ 6.0	13	6.5	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	M	For nitrile examination gloves: ≥ 6.0	13	6.3	Passed

REMARKS:

1. Brand/ Model and Lot No. were not provided by client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Examination Gloves

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, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 26 January 2021

Test Report No. 7191256089-EEC21-WBH
dated 31 Mar 2021

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 Examination Gloves submitted by
Shandong Intco Medical Products Co., Ltd. on 15 Mar 2021

TESTED FOR:

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

TEST DATE:

17 Mar 2021 to 31 Mar 2021

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Examination Gloves	Nil	Blue	Nil	S	34	Shandong Intco Medical Products Co., Ltd.
2				Nil	L	35	
3				Nil	XL	34	

METHOD OF TEST:

EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
-Clause 4 Dimensions
-Clause 5 Strength

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

Phone : +65-6778 7777
E-mail: info.sg@tuvsud.com
https://www.tuvsud.com/sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
15 International Business Park
TÜV SÜD @ IBP
Singapore 609937

PSB Singapore

RESULTS:

Sample: Disposable Nitrile Examination Gloves

Table: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	S	≥ 240	13	248	Passed
		L		13	252	Passed
		XL		13	246	Passed
	b) Width (mm)	S	80 ± 10	13	84	Passed
		L	110 ± 10	13	104	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	S	For nitrile examination gloves: ≥ 6.0	13	6.1	Passed
		L		13	6.4	Passed
		XL		13	6.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	S	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		L		13	6.9	Passed
		XL		13	6.6	Passed

REMARKS:

1. Brand/ Model and Lot No. were not provided by client.

Yeo Poh Kwang
Associate Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Disposable Nitrile Examination Gloves

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, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.

6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

Effective 26 January 2021

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:

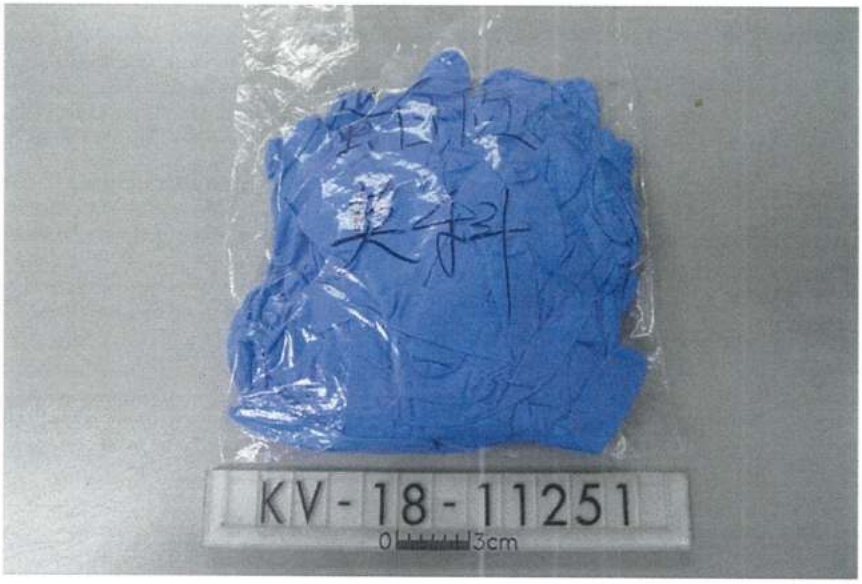
Ambient Temperature : (25 ± 2) ℃
Relative humidity : (50 ± 10) %

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 :



----- oOo -----

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

SGS Taiwan Ltd. 台灣檢驗科技股份有限公司 | No.61, Kai –Fa Road, Nanzih Export Processing Zone, Kaohsiung, Taiwan /高雄市楠梓加工出口區開發路61號
t (886-7) 301-2121 f (886-7) 301-1165 www.sgs.tw
Member of SGS Group

中国认可
国际互认
检测
TESTING
CNAS L0604

scan to see the report

QDHL2103500009MD

Test Report

Report No.: QDHL2103500009MD

Sample Description:	DISPOSABLE NITRILE EXAM GLOVES
Applicant:	SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
Test Type:	SUBMITTED BY CLIENT

Report No.: QDHL2103500009MD

Test Report

Sample information	Sample Description	DISPOSABLE NITRILE EXAM GLOVES	Color	NOT PROVIDED
	Received sample quantity/ Tested sample quantity	10PCS/ 5PCS	Type/ Specifications	S
	Lot No.	NOT PROVIDED	Lot Quantity	NOT PROVIDED
	Manufacture Date	NOT PROVIDED	Expiration Date	NOT PROVIDED
	Material/Appearance	NOT PROVIDED	Storage Condition	NOT PROVIDED
	Manufacturer	NOT PROVIDED		
	Others	NOT PROVIDED		
Client information	Applicant	SHANDONG INTCO MEDICAL PRODUCTS CO., LTD		
	Applicant address	NO.9888,QIWANG ROAD,NAOSHAN INDUSTRY PARK,QINGZHOU,SHANDONG,CHINA		

Report No.: QDHL2103500009MD

Test information	Sample Receiving Date	MAR.01,2021	Test Period Date	MAR.01,2021 TO MAR.05,2021
	Sample No.	QDHL2103500009MD	Test environment	Meet requirement
	Test items	Removable surface powder		
	Testing Accordance	EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: MAR.05,2021			
Remark	/			

Approver: Auditor: Compiler:

Date: 2021.03.05 Date: 2021.03.05 Date: 2021.03.05

Report No.: QDHL2103500009MD

Sample Photo

Report No.: QDHL2103500009MD

Test Results

Test Items	Unit	Test Method	Requirement	Test Result	Assessment
Removable surface powder	mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006	≤2	0.22	Pass

Remarks:

1. Finish of gloves: Powdered-free gloves (As per client's requirement).
2. The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

End of Report

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; no cross-page seal; altered;a copy without the red testing seal of SGS.

2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

3. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.

5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026599-1 **DATE : 19/12/2018**

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK,
QINGZHOU, SHANGDONG,
CHINA
A/C F615001 SGS CSTC STANDARDS TECHNICAL SERVICES CO. LTD
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
DISPOSABLE NITRILE GLOVE
COLOUR BLUE
PRODUCT CODE 69702457560
PHOTO APPENDIX.

SAMPLE RECD ON 22/05/2018 **TESTING PERIOD :** 22/05/2018 - 29/05/2018

Summary of Test Results/Conclusion		
Test Method / Standard	**Clause/Test Name**	**Status / Performance Level**
EN 16523-1:2015	**Permeation by Liquid chemical under conditions of continuous contact.**	
	Formaldehyde 37%	Level - 3

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

Test report revised to add product code & reporting details as per customer request.

This Report cancels and supersedes the Report No 9420026599 Dated 30/05/2018 issued by SGS India.

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
Regd & Corp. Off : SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel : (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026599-1 **DATE : 19/12/2018**

RESULTS

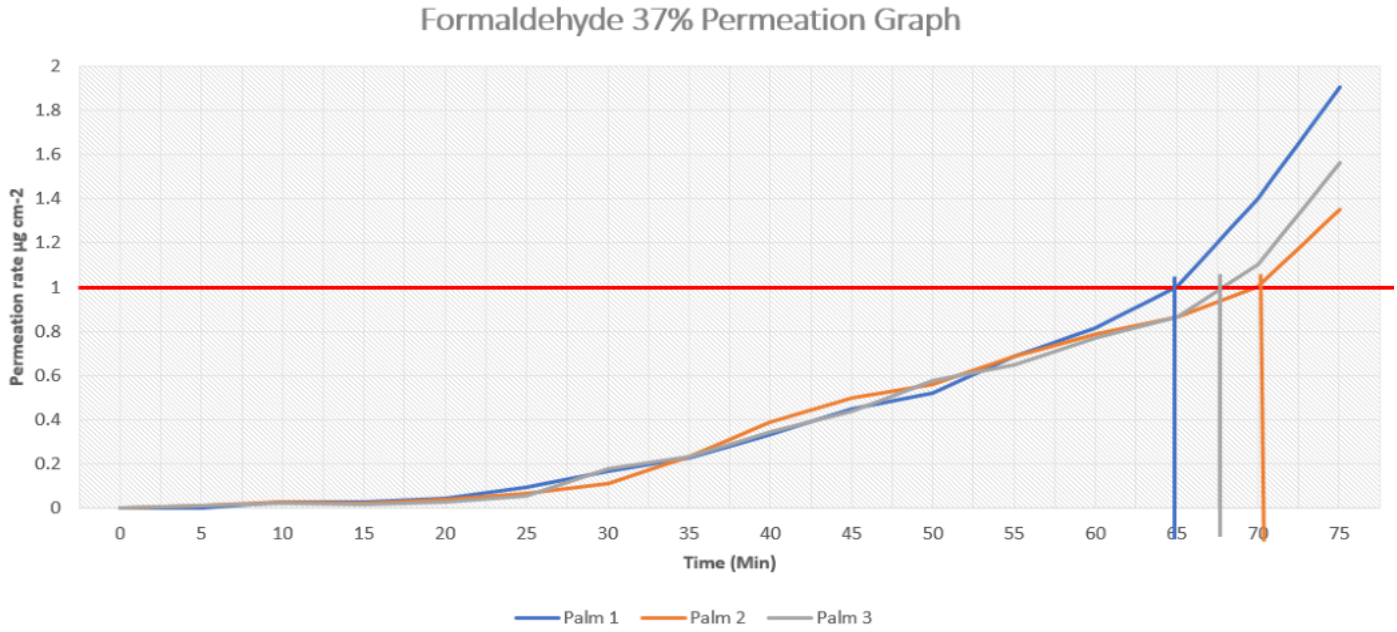
EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 µg cm^{-2} min^{-1} (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Formaldehyde 37% 50-00-0	Closed loop/ Grade 3 water	Periodic measurement with HPLC	0.11 0.10 0.10	65 70 68	Level - 3	Moderate Swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirments for chemical risks.
Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual results achived per chemical



***** End of Report*****

SGS India Pvt. Ltd. Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700
Regd & Corp. Off : SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel : (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026316-1 **DATE : 19/12/2018**

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK,
QINGZHOU, SHANGDONG,
CHINA
A/C F615001 SGS CSTC STANDARDS TECHNICAL SERVICES CO. LTD
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
DISPOSABLE NITRILE GLOVE
COLOUR BLUE
PRODUCT CODE 69702457560
PHOTO APPENDIX.

SAMPLE RECD ON 22/05/2018 **TESTING PERIOD :** 22/05/2018 - 29/05/2018

Summary of Test Results/Conclusion		
Test Method / Standard	**Clause/Test Name**	**Status / Performance Level**
EN 16523-1:2015	**Permeation by Liquid chemical under conditions of continuous contact.**	
	Hydrogen peroxide 30%	Level - 2

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
ASST. MANAGER
Email your Test Report Related Enquiries at Feedback.SLT@sgs.com

Test report revised to add product code & reporting details as per customer request.

This Report cancels and supersedes the Report No 9420026316 Dated 29/05/2018 issued by SGS India.

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
Regd & Corp. Off : SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel : (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)

"NABL ACCREDITED
Certificate No. TC-6176"

Revised report.

TEST REPORT

Report No. : CH:TX:9420026316-1 **DATE : 19/12/2018**

RESULTS

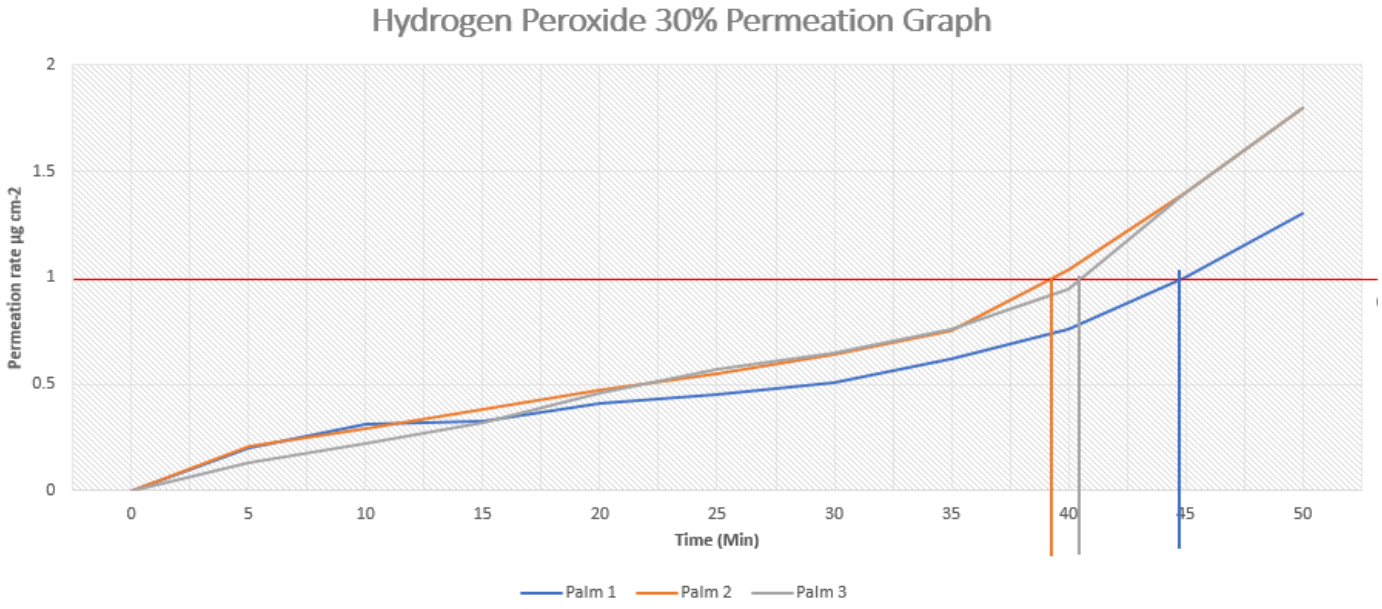
EN 16523-1:2015 Determination of material resistance to permeation by chemicals – Part-1: Permeation by Liquid chemical under conditions of Continuous contact.

Chemical CAS NO	Loop system/collection medium	Analytical technique used	Mean thickness (mm)	NBT at NPR 1.0 µg cm^{-2} min^{-1} (minutes)	Performance level accordance to EN ISO 374-1: 2016 Table 1	Observation
Hydrogen Peroxide 30% 7722-84-1	Closed loop/ Grade 3 water	Continuous measurement with Redox Electrode	0.10 0.09 0.09	45 39 41	Level - 2	Moderate Swelling

EN ISO 374-1:2016 – Protective gloves against dangerous chemicals and micro-organisms.
Part 1: Terminology and performance requirments for chemical risks.
Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

Performance levels are based on the lowest individual results achived per chemical.



***** End of Report*****

SGS India Pvt. Ltd. **Consumer & Retail, 28 B/1 (SP), 28 B/2 (SP), Second Main Road, Ambattur Industrial Estate, Ambattur, Chennai – 600 058. Phone : 91-44-66081600,Fax :91-44-66081700**
Regd & Corp. Off : SGS House, 4B, A.S. Marg, Vikhroli (West), Mumbai-400083. Tel : (022) 66408888 Fax : (022) 66408829 www.sgs.com
Member of the SGS Group (SGS SA)