



Powder-free disposable nitrile examination gloves



Manufactured by:
**Shandong Intco Medical Products
Co., Ltd**
No.9888 Qiwang Road, Naoshan
Industry Park
Qingzhou 262506
Shandong China

Distributed by:
Global Tooling Service s.r.o
Na Folimance 2155/15,
Vinohrady (Praha 2), 120 00
Praha

Product Information

MedCare powder-free disposable nitrile gloves

Spec code : NBR-PT-40-WH

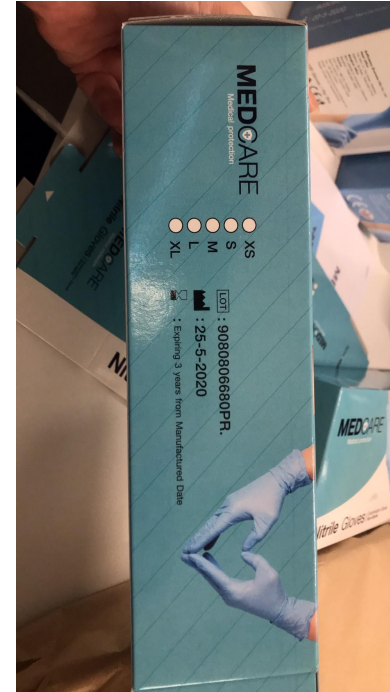
Non – Latex

Ambidextrous

Protein Free

Textured

Size: XS/S/M/L/XL



Product Specification

MedCare powder-free disposable nitrile gloves

| NITRILE EXAMINATION GLOVES, POWDER FREE, NON-STERILE | | |
|--|---|----------------------------------|
| Design and Feature | | |
| Type | Antibiotous, texture surface at fingers (F1) and beaded cuff | |
| Material | Powder free and non-sterile examination gloves | |
| Material | 100% nitrile (Acrylonitrile-butadiene) | |
| Color | Blue OR Off-White depending on availability | |
| Surface Treatment | | |
| Observation on donning side | F1 | |
| Dimension | | |
| Size | Palm width (mm) | Length (mm) |
| XS | 80 | Min. 240 |
| S | 85±10 | Min. 240 |
| M | 90±10 | Min. 240 |
| L | 110±10 | Min. 240 |
| XL | 111±10 | Min. 240 |
| Weight | | |
| Size | Weight (g) | |
| XS | 2.6±0.3 | |
| S | 3.0±0.3 | |
| M | 3.0±0.3 | |
| L | 4.0±0.3 | |
| XL | 4.5±0.3 | |
| Single-wall | | |
| Thickness (mm) | Finger | Spec |
| | Palm | Min. 0.205 |
| | Cuff | Min. 0.205 |
| | | Min. 0.205 |
| Physical Properties | | |
| | Before Aging | EN4551M Spec |
| Tensile Strength (MPa) | | Min 14 |
| Elongation (%) | | Min 500 |
| Force at break (N) | | Min 6 |
| Physical Properties | | |
| | After Aging | EN4551M Spec |
| Tensile Strength (MPa) | | Min 14 |
| Elongation (%) | | Min 400 |
| Force at break (N) | | Min 6 |
| Packing Mode | | |
| | 100 gloves by weight per dispenser and 10 per carton | |
| Lot # identification on Finished Goods | | |
| | No marking | |
| | Lot Number Structure | YMPPPPSS (9 digits) |
| | Y | = Year of Packing |
| | M | = Month of Packing |
| | PPPP | WSP's Packing Work Order # (PWG) |
| Recommended Shelf Life | | |
| | 5 years upon manufactured date. | |
| Pre-shipment inspection | | |
| Dimension | N-13, Median | |
| Physical Properties | N-13, Median | |
| 100ml Water Leak | G-I, AQL 1.5 – AQL 4.0 | |
| *Single-Normal | N=0 | |
| Sampling Plan | Major Visual Inspection G-I, AQL 2.5 | |
| Minor Visual Inspection | G-I, AQL 4.0 | |
| Product Conformance | | |
| | <ul style="list-style-type: none"> Medical Device in compliance with European Medical Device Directive 93/42/EEC (CE Class I) EN455 Parts 1, 2, 3 and 4 Personal Protective Equipment of Complex Design Category II, in European Regulation (EU) 2016/425, type test to EN430:2003+A1:2009, EN ISO 374-1:2016 Type 1, EN 374-2:2014, EN 374-3:2013, EN 374-5:2016 & EN 16523-1:2015, CE 2797 ASTM D6319 US FDA Quality System Regulation (QSR) ISO9001 Quality Management Systems ISO 14845 Quality Management Systems | |
| Quality Assurance | | |

Note: The Above information is a guideline of typical performance value and characteristics of the product, and not to be used as actual product specifications.

| Characteristic | Inspection level | AQL |
|--|------------------|---------|
| Freedom from holes | G 1 | 1.5-2.5 |
| Dimension (width, length, thickness) | S-2 | 4.0 |
| Physical properties (before and after accelerated aging) | S-2 | 4.0 |
| Powder amount | n=2 | N/A |
| Protein content | ASTM-n=3 | N/A |

| Dimensions | Size | Width(mm) | Minimum length(mm) | Thickness(mm.) | | Weight(g.) |
|------------|------|-----------|--------------------|----------------|------------|------------|
| | | | | Palm | Finger | |
| | XS | 75+ 5 | 240 Min | 0.08 Min | 0.10+ 0.02 | 3.90-4.30 |
| | S | 85+ 5 | 240 Min | 0.08 Min | 0.10+ 0.02 | 4.20-4.60 |
| | M | 95+ 5 | 240 Min | 0.08 Min | 0.10+ 0.02 | 4.80-5.20 |
| | L | 106+ 5 | 240 Min | 0.08 Min | 0.10+ 0.02 | 5.30-5.70 |
| | XL | 115+ 5 | 240 Min | 0.08 Min | 0.10+ 0.02 | 5.70-6.10 |

| Physical properties | | |
|--------------------------|-------------|---|
| ISO 11193-1: TIS1056 | ASTM D 3578 | BS EN 455-2 |
| Before accelerated aging | | |
| Force at break (N) | 7.0 Min | Stress at 500% Elongation (MPa) 5.5 Max |
| Elongation at break (%) | 650 Min | Tensile strength (MPa) 18 Min |
| | | Force at break (N) 6.0 Min |
| | | Elongation at break (%) 650 Min |
| After accelerated aging | | |
| Force at break (N) | 6.0 Min | Tensile strength (MPa) 14 Min |
| Elongation at break (%) | 500 Min | Elongation at break (%) 500 Min |
| | | Force at break (N) 6.0 Min |

| Powder Content | |
|-----------------|---------------------------|
| Type | ASTM D6124 |
| Powdered gloves | 10 mg/dm ² Max |

| Protein Content | |
|-----------------|----------------------------|
| Type | ASTM D5712 |
| Powdered gloves | 200 ug/dm ² Max |

Material Safety Data

MedCare powder-free disposable nitrile gloves

Physical Data:

Nitrile Butadiene Rubber :
95.8%
Sulfur : 1%
Zinc Oxide : 1.2%
Accelerators : 1%
Others : 1%
Donning Agent : Food Grade
Absorbable Dusting Power USP
Cornstarch (Powder Nitrile
Examination Gloves Only)

Fire & Explosion:


Stability: Stable
Flash Point: N.A
Extinguishing Media:
Foam, Carbon Dioxide,
Water

Normal Precautions:

Ventilation: Stable
Equipment: Not necessary
Spill / Clean Up: N/A
Eyes: N/A
Storage: No special
precautions necessary; store at
room temperature.

Certification (TUV Rheinland)

MedCare powder-free disposable nitrile gloves


TUV Rheinland
Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002


Organization: Inteo Industrie Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope: Sites included:
INTCO (Shanghai) Machinery Co., Ltd.
No. 77 Yaoshuikuo Road, Dayang Shengjiao,
Jiangsu Province 212133, China
Manufacture of: Wheelchairs, Cold Packs, Hot Packs, Hot/Cold
Packs, Cool Gel Mats, Warmers

Certification Body

X. Ren

Date: 2012-11-13



TUV Rheinland
Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg


Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization: Inteo Industrie Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope: Products:
- Disposable Electrocardiogram Active Electrode
(Electrocardiogram Pencil)
- Disposable Patient Plate (Grounding Pad)
- Disposable ECG Electrode
- Wheelchairs
- Cold Packs
- Hot Packs
- Hot/Cold Packs
- Warmers
- Examination Glove
- Disposable Non-woven Products
- Cool Gel Mats
- Hot/cold Pads
- Cooling Patch

Certification Body

X. Ren

Date: 2012-11-13



TUV Rheinland
Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg


Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization: Inteo Industrie Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope: Sites included:
Shanghai Inteco Electrode Manufacturing Co., Ltd.
No. 1368, Rubin Road, Pengxian District
Shanghai 201417, P. R. China
Manufacture of Disposable ECG Electrode, Disposable
Electrocardiogram Active Electrode (Disposable
Electrocardiogram Pencil), Disposable Patient Plate
(Grounding Pad)
Shanghai Inteco Medical Supply Co., Ltd.
No. 1358, Rubin Road, Pengxian District
Shanghai 201417, P. R. China
Manufacture of Cold Packs and Hot Packs, Hot/Cold
Packs, Warmers, Hot/Cold Pads

Certification Body

X. Ren

Date: 2012-11-13



TUV Rheinland
Doc. 1/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60079436 0001
Report No.: 15044656 002

Organization: Inteo Industrie Co., Ltd.
3F., Building 9, Block F,
No.188 Xinjun Ring Rd., Minhang
201114 Shanghai
China

Scope: Sites included:
INTCO (Shanghai) Machinery Co., Ltd.
No. 77 Yaoshuikuo Road, Dayang Shengjiao,
Jiangsu Province 212133, China
Manufacture of Wheelchairs, Cold Packs, Hot Packs, Hot/Cold
Packs, Cool Gel Mats, Warmers

Certification Body

X. Ren

Date: 2012-11-13

Certification (TUV Rheinland - EC certificate)


TÜVRheinland®

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60087401 0001
Report No.: 15044656 003

Manufacturer: Intco Medical (HK) Co., Limited
Unit 04, 7/F Bright Way Tower
No. 33 Mong Kok Rd.
KL
Hong Kong

Products: Medical Devices
(see attachment for products and additional sites)
Replaces Approval, Registration No.: ED 60038675 0001

Expiry Date: 2016-08-21

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2013-11-04
Date: 2013-11-04


TÜVRheinland LGA Products
Notified Body
X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the Identification number 0197.

Certification (TUV Singapore)

MedCare powder-free disposable nitrile

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



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 PSE Pte. Ltd. In addition, this report is governed by the laws of our office location.

SUBJECT:

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

TESTED FOR:

Shandong Intra Medical Products Co., Ltd.
No. 8888 Qingang Road
Nanhai 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 | J | M | 217 | Shandong Intra Medical Products Co., Ltd. |

Lot size as specified by client: 35,001 to 100,000 pieces.

METHOD OF TEST:

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

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



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 | Freedom from holes | Shall not leak | 7 | 200 | 0 | Passed |

REMARKS:

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

Yao Puh Kwang
Higher Associate Engineer

Wong Bee Hai
Product Manager
Medical Health Services (NMM)

APPENDIX:



Photo: Disposable Nitrile Glove, Size M

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



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

- This report applies to the sample of the specific product/equipment given at the time of its testing/calculation. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such items may not be used to indicate or imply that TÜV SÜD PSE supports, recommends or endorses the manufacture, supplier or user of such product/equipment, or that TÜV SÜD PSE in any way guarantees the best performance of the product/equipment. Clauses otherwise stated in the report, on the other hand, are conducted to determine long term effects of using the specific product/equipment.
- The samples mentioned in the report were submitted and manufactured by the Client. TÜV SÜD PSE therefore assumes no responsibility for the accuracy of information on the brand name, model number, signs of manufacture, component or any information supplied.
- Nothing in this report shall be interpreted to mean that TÜV SÜD PSE has verified or ascertained any endorsement or results from any other testing Authority or bodies that may be found on that sample.
- This report shall only be reproduced, copied, or used and no reference shall be made by the Client to TÜV SÜD PSE or to the report or results furnished by TÜV SÜD PSE in any advertisement or sales promotion.
- Unless otherwise stated, the tests were carried out at TÜV SÜD PSE Pte. Ltd., No. 1 Science Park Drive Singapore 118221.

July 2011




Laboratory:
TUV SUD PSE Pte. Ltd.
No. 1 Science Park Drive
Singapore 118221

Phone: +65 6881 1333
Fax: +65 6881 8600
Email: registration@tuv-sud.sg
www.tuv-sud.sg
Co. Reg. 1982282N

Regional Head Office:
TUV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive #01-01
Singapore 118221
SUD

Certification (Satra Technology) MedCare powder-free disposable nitrile gloves


 Issued to: Shandong IntraMedical Products Co., Ltd
 Qingdao Road, Naozhen Industrial Park
 Qingdao
 Shandong
 262000
 China

Validity code: 2777
 SATRA customer number: P1720

EU Type-Examination Certificate

Certificate number: 2777/11030-03/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 II product.

Product reference: Description: Disposable vinyl Powdered and Powder-Free, non-sterile gloves

Clear – 69724575 XXXX
 Yellow – 69724575 XXXX
 Blue – 69724575 XXX
 White – 69724575 XXXX

| Size | Blue | White | Clear | Yellow | Classification | Level | Degradation % |
|-------|------|-------|-------|--------|---------------------------------------|-------|---------------|
| 6 XS | 221 | 231 | 201 | 211 | EN ISO 374-2:2016 Type B | 6 | <19 |
| 7 S | 222 | 232 | 202 | 212 | Sodium Hydroxide 4% (K) | 6 | <19 |
| 8 M | 223 | 233 | 203 | 213 | Hydrogen peroxide 30% (P) | 2 | <23 |
| 9 L | 224 | 234 | 204 | 214 | Formaldehyde 37% (T) | 3 | 19.2 |
| 10 XL | 225 | 235 | 205 | 215 | EN ISO 374-2:2016 | Pass | |
| | | | | | Protection against bacteria and fungi | Pass | |
| | | | | | Protection against viruses | Pass | |

Standard/Technical specifications applied:
 EN 420: 2003+A1: 2009, EN 388:2016, EN ISO 374-1:2016, EN ISO 374-2:2016

Technical specifications documents:
 BSG: CH TX 7420016648, CH TX 742016055, ODH 1703039397, ODH 1703000880, CH TX 942002461-1,
 CH TX 94200260, CH TX 942002996, CH TX 103003689
 SATRA: CH120224481814, CH1202385381101, CH1202385381102,
 TXV 721648574, TXV2024648574-WP-CAL, TXV2021669-CAL-175

Signed on behalf of SATRA: *Chunlei Bao*, Anita Brennan, *Chunlei Bao*, Jacques Glasspoff
 Date first issued: 06/09/2018
 Date of issue: 06/10/2020
 Expiry date: 06/09/2023

SATRA Training Centre Limited, Bentley Business Park, 2000, 2000 Westgate Road, Basingstoke, Hampshire, RG24 0BA, UK



PPE REGULATION (EU) 2016/425 MODULE C2 CERTIFICATE

Issued to: Shandong IntraMedical Products Co Ltd
 Qingdao Road, Naozhen Industrial Park
 Qingdao
 Shandong
 China
 262000

This is to certify that the following products tested under SATRA reports referenced: STE0293607 & CH18029484(2009) 211 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the first product for and on behalf of SATRA Technology Europe Limited

| EU TYPE EXAMINATION CERTIFICATE NUMBER | PRODUCT GROUP REFERENCE | PRODUCT TYPE | CLASSIFICATION |
|--|-------------------------|-----------------------|---|
| | 69724575 | | |
| 2777/11030-03/E00-00 | Blue 69724575 601-605 | Disposable nitrile | EN ISO 374- 1:2016+A1:2018 Type B |
| | Yellow 69724575 631-635 | Non-sterile glove | |
| | White 69724575 641-645 | | |
| | Black 69724575 651-655 | | |

Dated: 09 March 2020 This certificate is valid until: March 2021


Signed By: *Alan Weston*
 Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited



The issuance of this certificate is subject to the company meeting the requirements of the PPE Regulation (EU) 2016/425 and the manufacturing and quality systems in the required scope. SATRA Technology Europe Limited, Bentley Business Park, 2000, 2000 Westgate Road, Basingstoke, Hampshire, RG24 0BA, UK. SATRA is a member of the British Standards Institution (BSI).

NQA Compliance Report



Compliance Report

Applicant: Shandong INTCO Medical Products Co., Ltd.
Address: QIWANG ROAD, NAO SHAN INDUSTRIAL PARK,
QINGZHOU, SHANDONG, 262500, CHINA

Product: Disposable Nitrile Examination Gloves (non-sterile)
Type: S, M, L, XL

Product Classification: Class I


The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affixes the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. **01982**
Initial Issue Date: **24 Oct 2012**


General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.

EC Declaration of Conformity



Document Number : INTCO-CE-DC-NBR-001

Version: A/0

EC DECLARATION OF CONFORMITY

Manufacturer

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

Authorized Representative

Name: Lotus NL B.V.
Address: Koningslaan Julianaplein 10, le Verd, 2995AA, The Hague Netherlands

Declares that the MDD described hereafter

Product name and model:

Disposable NBR Gloves

UMDNS code: 11882

Meet the provisions of the Council Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



CONFORMITY ASSESSMENT ROUTE: 93/42 EEC , 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 Inteco Medical Products Co., Ltd.
Address: Qiwang Road, Naoshan Industrial Park, Qingzhou, Shandong, China

Shandong, 2019-04-08

Place, date

Chi Yongtao, Plant Manager

Legally binding signature, Function

EC Declaration of Conformity

Certification (SGS) - Physical Property Test II

SGS

Test Report No.: QDHL1900154610T Date: SEP-25-2019 Page: 1 of 3

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD
NO.988, QIWANG ROAD, NAOZHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

The following sample(s) was/were submitted and identified by the client as:
Sample Description : METRICUMARD 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 MEET 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.

Zhou Xinkuan

Zhou Xinkuan, SK
Lab Manager



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd. is a member of the SGS Group (SGS S.A.).

Member of the SGS Group (SGS S.A.)

SGS

Test Report No.: QDHL1900154610T Date: SEP-25-2019 Page: 2 of 3

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 Item | Result | Note |
|--------|--|--------|------|
| 4 | Strength | Pass | --- |
| 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

| 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



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd. is a member of the SGS Group (SGS S.A.).

Member of the SGS Group (SGS S.A.)

SGS

Test Report No.: QDHL1900154610T Date: SEP-25-2019 Page: 3 of 3

Requirements: see table 3

Table 3 — Median values of force at break

| Throughout shelf life tested according to 5.2 and within 12 months of production tested according to 5.3 | Force at break (N/force) | | |
|--|--------------------------|-------|------------------------------|
| | Surgical gloves | | Examination/procedure gloves |
| | a) | b) | c) |
| | ≥ 9.0 | ≥ 6.0 | ≥ 5.5 |

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

Sample Photo:



SGS authenticates the photo on original report only

End of Report



SGS-CSTC Standards Technical Services (Qingdao) Co., Ltd. is a member of the SGS Group (SGS S.A.).

Member of the SGS Group (SGS S.A.)

Certification (SGS) - Aqueous extractable Protein

SGS
Material and Engineering Laboratory-Kaohsiung

Test Report

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

Shandong Inteco Medical Products Co., Ltd.
No.888, Qiu-ang Road, Nanshan 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.

SGS Taiwan Ltd.

100 Zhongxing Rd., No. 8, 10th Floor, North Hsiao-Feng Industrial Area, Songshan District, Taipei City 100, Taiwan R.O.C. (R.E.PUBLIC OF CHINA)
100 Zhongxing Rd., No. 8, 10th Floor, North Hsiao-Feng Industrial Area, Songshan District, Taipei City 100, Taiwan R.O.C. (R.E.PUBLIC OF CHINA)
100 Zhongxing Rd., No. 8, 10th Floor, North Hsiao-Feng Industrial Area, Songshan District, Taipei City 100, Taiwan R.O.C. (R.E.PUBLIC OF CHINA)

SGS
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) °C
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 :



----- (C) -----

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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Packing Information