

Nitrilhandschuhe



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info@praeventionmitkopf.de
USt-IdNr.: DE319005928
Steuernummer: 29/076/40297

PRODUKTBILDER

Technische Produktinfos:

Modell:	INTCO Medical
Farbe:	Blau
Material:	100% latexfrei puderfreies Nitril
Qualitäts Standard:	EN 455 EN 374 EN 420 ASTM D6319 Directive 93/42/EEC





CE (Medical Device)
2777 (Personal Protective Equipment)



Disposable Nitrile Exam Gloves Einmal-Nitril Untersuchungshandschuhe

100 Gloves/Box
Handschuhe/Packung

10 Boxes/Case
Packungen/Verpackungseinheit

VIOLET · VIOLETT

REF NG350EM

MDR (EU) 2017/745 (Class II: SN-455)



SN
455

MD

AQL
1.5



EC REP European Authorized Representative
Lotus NL B.V.
Königin Wilhelminaplein 10, 1e Verd, 2595AA, The Hague
Netherlands
info@lotusnl.com

PPE Regulation (EU) / PSA-Verordnung (EU) 2016/425 (Cat. III) EN 420:2003 (A1:2005)



SATRA Technology Europe Ltd.
Bretton Business Park, Chesham
 Bucks HP8 4NR (Windsor Road) 27771

Declaration of conformity: Further information are available at
Konformitätserklärung / weitere Informationen finden Sie unter:
www.intco-medical.com/downloads/zh.html

Shandong INTCO Medical Products Co., Ltd.
www.intco-medical.com
27771 Shandong Province, China
Shandong INTCO Medical Products Co., Ltd.
27771 Shandong Province, China
Shandong INTCO Medical Products Co., Ltd.



CE (Medical Device)
2777 (Personal Protective Equipment)



Disposable Nitrile Exam Gloves
Einmal-Nitril Untersuchungshandschuhe



Disposable
Einmal-Nit

Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 1 of 3

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.




Zhou Xinkuan, SK
Lab Manager



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sgs.china@sgs.com

Test Report

No.: QDHL1909015461OT

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 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



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Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 3 of 3

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



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End of Report



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



PSB Singapore

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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



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

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Fax : +65-6776 8670
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Co. Reg : 199002667R

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

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



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

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





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 affix's 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

A handwritten signature in blue ink, appearing to read 'H. Santos', is written over a horizontal line.

General Manager (Signature)



Test Report

No.: SHHG1512047994MD

Date: DEC. 09, 2015

Page: 1 of 3

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description : NITRILE GLOVES
SGS Ref. No. : QDHG1512005952OT
Sample Receiving Date : DEC. 03, 2015
Testing Period : DEC. 03, 2015 TO DEC. 09, 2015
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : POWDER (EN 455-3-2006 MEDICAL GLOVES FOR
SINGLE USE—PART 3:REQUIREMENTS AND TESTING
FOR BIOLOGICAL EVALUATION CLAUSE 4.4)
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE
FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE TEST
REQUIREMENT.

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng
Technical Manager



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Test Report

No.: SHHG1512047994MD

Date: DEC. 09, 2015

Page: 2 of 3

Test Conducted:

EN 455-3-2006 Medical gloves for single use—Part 3:Requirements and testing for biological evaluation

Number of test sample	:	5 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Defects observed before testing	:	No defects
Test Result	:	Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1

Note:

1. Test according to EN ISO 21171-2006.
2. The quantity of powder was 0.2mg<2mg.



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Test Report

No.: SHHG1512047994MD

Date: DEC. 09, 2015

Page: 3 of 3

Sample Photo:

Received sample



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End of Report

Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 1 of 3

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.




Zhou Xinkuan, SK
Lab Manager



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Test Report

No.: QDHL1909015461OT

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 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



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Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 3 of 3

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



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 1 of 6

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description : DISPOSABLE NITRILE MEDICAL EXAMINATION GLOVES
 SGS Ref. No. : QDHL1609006834OT
 Style/ Item No. : S、M、L、XL
 Sample Receiving Date : SEP. 18, 2016
 Testing Period : SEP. 18, 2016 TO OCT. 13, 2016
 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) : FOR FURTHER DETAILS, PLEASE REFER TO THE
 FOLLOWING PAGE(S)
 Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Signed for and on behalf of
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.



Melody Zhang
 Authorized Signatory



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 2 of 6

Test Conducted

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

Number of test sample	:	78 pcs
Type	:	examination/procedure gloves
The manufacturing batch code	:	/
Size	:	S, M, L, XL
Defects observed before testing	:	No defect
Test Result	:	Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#1
5	Strength	Pass	#2, #3
7	Labeling	N/C	#4

Notes : # 1 See result 1
 # 2 See result 2
 # 3 As per client's declare, these gloves (four size: XS, S, M, L, XL) only size different, the material is the same, and only the glove of size M was tested.
 # 4 N/C means not conducted as per client's requirement.



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 3 of 6

Test Result:

1. Dimensions

Sample Quantity: 52 pcs

Size	S												
Length(mm)	242	240	241	245	241	241	242	240	242	240	240	242	240
Width(mm)	85	85	86	86	85	86	86	86	85	85	85	84	85

Median value:

Length (mm): 241

Width (mm): 85

Size	M												
Length(mm)	244	243	240	243	245	243	241	240	244	245	240	244	246
Width(mm)	98	97	98	98	96	97	98	97	98	98	98	98	98

Median value:

Length (mm): 243

Width (mm): 98

Size	L												
Length(mm)	243	247	249	250	245	245	247	253	250	250	243	250	245
Width(mm)	105	109	106	109	107	108	107	108	103	108	108	108	105

Median value:

Length (mm): 247

Width (mm): 108

Size	XL												
Length(mm)	250	256	250	258	255	250	265	252	250	250	248	252	260
Width(mm)	117	117	115	120	117	117	117	118	117	116	114	117	117

Median value:

Length (mm): 252

Width (mm): 117

Requirements: see table 1&2



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 4 of 6

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥ 250	67 ± 4
5.5	≥ 250	72 ± 4
6	≥ 260	77 ± 5
6.5	≥ 260	83 ± 5
7	≥ 270	89 ± 5
7.5	≥ 270	95 ± 5
8	≥ 270	102 ± 6
8.5	≥ 280	108 ± 6
9	≥ 280	114 ± 6
9.5	≥ 280	121 ± 6

**Table 2 Dimensions for
examination/procedure gloves**

Size	Median length in mm	Median width in mm
Extra small	≥ 240	≤ 80
Small		80 ± 10
Medium		95 ± 10
Large		110 ± 10
Extra Large		≥ 110



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 5 of 6

2. Strength

Sample Quantity: 26 pcs

Size	M												
Force at break(N)	7.279	3.922	4.901	7.438	4.688	8.478	5.367	3.436	7.098	8.918	7.871	8.763	4.397
Force at break after challenge testing(N)	5.736	5.594	6.649	3.298	5.874	3.306	7.962	8.171	8.004	8.092	6.803	8.964	10.89

Median value:

Force at break during shelf life (N): 7.098

Force at break after challenge testing (N): 6.803

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).			



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Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 6 of 6

Sample Photo:

Received sample (Size S)



Received sample (Size M)



Received sample (Size L)



Received sample (Size XL)



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End of Report



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dated 01 Mar 2019



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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



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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

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