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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

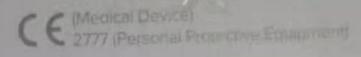
ASTM D6319

Directive 93/42/EEC







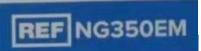




Disposable Nitrile Exam Gloves Einmal-Nitril Untersuchungshandschuhe

100 Gloves/Box Handschuhe/Packung

Boxes/Case 10 Packungen/Verpackungseinheit VIOLET · VIOLETT



MDR (EU) 2017/745 (Class (1.5%-455

























EC REP European Authorised Representative

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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

: EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE - PART 2: Test Requested

REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES

Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)

: THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT. Conclusion

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	:	1
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

<u>Clause</u>	<u>Test Items</u>	<u>Result</u>	<u>Note</u>
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 glov 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.
- 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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PSB Singapore

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Add value. Inspire trust.

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	7)	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 Pte. Ltd. No.1 Science Park Drive Singapore 118221

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



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.
- 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.
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- 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

General Manager (Signature)

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



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.

udens



Technical Manager





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:

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



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f (86-21) 54500353

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Test Report

No.: SHHG1512047994MD

Date: DEC. 09, 2015 Page: 3 of 3

Sample Photo:

Received sample



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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)		examination/procedure gloves c)
Manufacturing batch code	:	1
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

<u>Clause</u>	<u>Test Items</u>	<u>Result</u>	<u>Note</u>
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.
- 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 PROPERTIE

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





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 propertie

Number of test sample	:	78 pcs
Туре	• •	examination/procedure gloves
The manufacturing batch code	• •	1
Size	• •	S, M, L, XL
Defects observed before testing	:	No defect
Test Result	:	Pass

Clause	l est 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	2 240 241 245 241 241 242 240 242 240 240 242 240											
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	4 243 240 243 245 243 241 240 244 245 240 244 246											
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	Median width
	in mm	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	Median width
	in mm	in mm
Extra small		≤80
Small		80±10
Medium	≥240	95±10
Large		110±10
Extra Large		≥110



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2. Strength

Sample Quantity: 26 pcs

Size							М						
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/pro	cedure gloves	
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	

- Requirements for all surgical gloves.
- 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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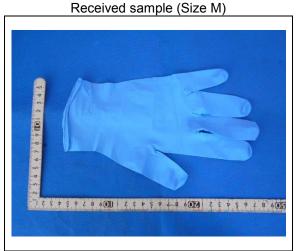


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Sample Photo:

Received sample (Size S)





Received sample (Size L)



Received sample (Size XL)



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End of Report



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



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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July 2011

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