

EC Declaration of Conformity

Manufacturer:

Shenzhen Shiqiao Science and Technology Co. LTD
B2904, Nanshan Software Park, No.10128, Shennan
Avenue, Liancheng Community, Nantou Street,
Nanshan District, Shenzhen

Mikki, Wan Sin Nam
Tel: +0755 28688295 E-mail:enquiry@wmgroupltd

whose single Authorized EU-Representative:

M/s CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N° 18, CP 29006, Málaga,
Spain

We, the manufacturer, herewith declare that the products

Disposable Nitrile Gloves

SQKC006

UMDNS code:11882

Meet the provisions of 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

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

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

Shenzhen Shiqiao Science and Technology Co. LTD

B2904, Nanshan Software Park, No.10128, Shennan Avenue, Liancheng Community, Nantou Street,
Nanshan District, Shenzhen

Shenzhen 2020/08/10
Place, date


President Mikki Wan Sin Nam
Legally binding signature, Function





中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report

No.: QDHL2008007820MD

Date: AUG.21,2020

Page: 1 of 2

SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY CO., LTD.
B2904, NANSHAN SOFTWARE PARK, NO.10128, SHENNAN AVENUE,
LIANCHENG COMMUNITY, NANTOU STREET, NANSHAN DISTRICT, SHENZHEN

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

Sample Description	: MEDICAL NITRILE INSPECTION GLOVES
Style No.	: SQKC006
Lot No.	: 20200707
Lot Size	: NOT PROVIDED
Sample Quantity	: 300PCS
Sample Receiving Date	: AUG.06,2020
Testing Period	: AUG.06,2020 TO AUG.21,2020

Test Requested

BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and
Testing for Freedom from Holes (Clause 5.1)

Result

Pass

Remark: - 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.

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

Jessica Gao



Jessica Gao
Approved Signatory



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

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Member of the SGS Group (SGS SA)

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Test Report

No.: QDHL2008007820MD

Date: AUG.21,2020

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Test Conducted:

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

Number of test sample	:	200 PCS
Sample size	:	M
Number of non-conforming gloves	:	1 PC

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note	:	1	Sample quantity: 200 PCS, AQL:1.5, Ac:7, Re:8, Found: 1 PC. The sample selecting amount for this clause is deviated to 200 pcs per size as assessed by SGS.
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Sample Photo:

Received Sample



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LIANCHENG COMMUNITY, NANTOU STREET, NANSHAN DISTRICT, SHENZHEN

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

Sample Description	: MEDICAL NITRILE INSPECTION GLOVES
Style No.	: SQKC006
Lot No.	: 20200707
Lot Size	: NOT PROVIDED
Sample Quantity	: 200 PCS
Sample Receiving Date	: AUG.06,2020
Testing Period	: AUG.06,2020 TO AUG.21,2020

Test Requested

BS EN 455-2:2015 Medical Gloves for Single Use – Part 2: Requirements and
Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3)

Result

Pass

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Technical Services (Qingdao)
Co., Ltd.



Jessica Gao
Approved Signatory

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Test Report

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Test Conducted:

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

Number of test sample	:	26 pcs
Type	:	Examination/procedure gloves: b)
Size	:	Examination/procedure gloves: M

Clause	Test Items	Result
4	Dimensions	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	M	
	Length (mm)	Width (mm)
No.		
1	244	94
2	247	95
3	244	95
4	242	96
5	241	95
6	246	95
7	242	95
8	241	94
9	238	94
10	241	95
11	245	94
12	239	95
13	241	94
Standard requirement	≥240	95±10
Median value	242	95

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Result 2: Strength

Size: M			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	5.9	1	5.4
2	6.9	2	6.4
3	5.3	3	6.0
4	7.0	4	6.8
5	6.9	5	5.5
6	6.2	6	6.1
7	6.2	7	6.1
8	5.6	8	5.4
9	6.8	9	4.9
10	6.4	10	4.9
11	7.2	11	6.7
12	5.9	12	5.3
13	6.9	13	6.2
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	6.4	Median value	6.0

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

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QD 7389495

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Test Report

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SHENZHEN SHIQIAO SCIENCE AND TECHNOLOGY CO., LTD.
B2904, NANSHAN SOFTWARE PARK, NO.10128, SHENNAN AVENUE,
LIANCHENG COMMUNITY, NANTOU STREET, NANSHAN DISTRICT, SHENZHEN

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

Sample Description	: MEDICAL NITRILE INSPECTION GLOVES
SGS Ref. No.	: TAOHG2003373401
Style No.	: SQKC006
Lot No.	: 20200707
Lot Size	: NOT PROVIDED
Sample Quantity	: 200PCS
Sample Receiving Date	: AUG.06,2020
Test Performing Date	: AUG.06,2020 TO AUG.21,2020

Test Requested

BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and
Testing for Biological Evaluation (Clause 4.2*, 4.4, 4.5*)

Result

See Results

Remark: - 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.

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Jessica Gao
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Test Report

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Test Conducted:

BS EN 455-3:2015 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

Number of test sample	:	13 Pieces
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves
Size	:	M

Clause	Test Items	Result
4.2*	Chemicals	See Result 1
4.4	Powder-free gloves	Pass (See note 1)
4.5*	Proteins, leachable	See result 2

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.12mg. (Requirement: ≤2mg per powder-free glove)
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Result 1: Chemicals

Name	Cas No.	Concentration	Classification & Labelling
Information on ingredients of product:			
Acrylonitrile	107-13-1	55%	Carc. 1B, H350; Eye Dam. 1, H318; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335.
1,3-butadiene	106-99-0	40%	Muta. 1B, H340; Carc. 1A, H350
epoxy resin	38891-59-7	5%	No results found
Information on other substances used manufacturing process:			
Not provided			

The classification is according to the latest edition of Regulation (EC) No 1272/2008, and extended by company and literature data

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Result 2: Proteins, leachable

Test Item	Test Result
Determination of aqueous extractable protein($\mu\text{g/g}$)	Not Detected

Remark	:	1	$\mu\text{g/g}$ = microgram per gram.
		2	Detection limit of aqueous extractable protein is 10 $\mu\text{g/g}$

Remark:

- * Test items were not included in the CNAS accredited schedule for our laboratory.
- The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

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