

Manufacturer:

whose single Authorized EU-Representative:

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

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

Tel: +0755 28688295 E-mail:enquiry@wmgroup.ltd

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

0305500

EC Declaration of Conformity







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

: SQKC006 Style No. 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

Result Test Requested

BS EN 455-1:2000 Medical Gloves for Single Use - Part 1: Requirements and Pass

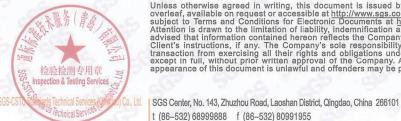
Testing for Freedom from Holes (Clause 5.1)

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 Approved Signatory



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中国认可 阿际互认 松洲 TESTING CNAS L0604

Test Report

No.: QDHL2008007820MD

Date: AUG.21,2020

Page: 2 of 2

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 av -,5,	
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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Date: AUG.21,2020

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

: MEDICAL NITRILE INSPECTION GLOVES Sample Description

Style No. : SQKC006 : 20200707 Lot No.

: NOT PROVIDED Lot Size

Sample Quantity : 200 PCS

Sample Receiving Date : AUG.06,2020

Testing Period : AUG.06,2020 TO AUG.21,2020

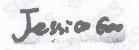
Test Requested Result

BS EN 455-2:2015 Medical Gloves for Single Use - Part 2: Requirements and Pass

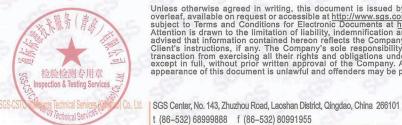
Testing for Physical Properties (Clause 4.2, 4.3, 5.2, 5.3)

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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No.: QDHL2008007821MD

Date: AUG.21,2020

Page: 2 of 4

Test Conducted:

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

Number of test sample	G :	26 pcs
Туре		Examination/procedure gloves: b)
Size : Examination/procedure gloves: M		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	e - 62 92 2 20 00
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	A CONTRACTOR OF THE CONTRACTOR	Λ	
No.	Length (mm)	Width (mm)	
1 6	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

200		Size: M	
	Ford	e at break (N)	
Befor	re aging	A	fter aging
No.	5 1 1	No.	
1 2 6	5.9	<u> </u>	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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Test Report No.: QDHL2008007822MD Date: AUG.21,2020 Page: 1 of 3

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

<u>Test Requested</u> <u>Result</u>

BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and See Results

Testing for Biological Evaluation (Clause 4.2*, 4.4, 4.5*)

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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Date: AUG.21,2020

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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	- 497	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
formation on ingredie	nts of product:	16° 9"	
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

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

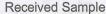
Test Item	Test Result
Determination of aqueous extractable protein(µg/g)	Not Detected

Remark	:	1	μg/g = microgram per gram.
, C	(37)	2	Detection limit of aqueous extractable protein is 10 µg/g

Remark:

- 1. * 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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