

EN455 Zertifikat für sunamed Nitril Handschuhe

sunamed Dokumenten Nummer:

sunamed1003

Aktuelle Version:

Auflage 1 Erstellt am: 10.9.2021

Mit Erscheinen dieser Version verlieren alle vorigen Versionen ihre Gültigkeit.

Gültig für nachfolgende Artikelnummern:


Gr.	EAN	Art.-Nr.		Artikel
S	4260274354544	1080	100 Handschuhe S blau Nitril MDR1 noP sunamed	100 Exam gloves S blue nitrile MDR1 noP sunamed
M	4260274354551	1081	100 Handschuhe M blau Nitril MDR1 noP sunamed	100 Exam gloves M blue nitrile MDR1 noP sunamed
L	4260274354568	1082	100 Handschuhe L blau Nitril MDR1 noP sunamed	100 Exam gloves L blue nitrile MDR1 noP sunamed
XL	4260274354575	1083	100 Handschuhe XL blau Nitril MDR1 noP sunamed	100 Exam gloves XL blue nitrile MDR1 noP sunamed

Abkürzungen:

MDR1 = MDR Klasse 1

noP = no Powder

EN455 Zertifikate



Test Report

No.: QDHL2004003693MD_EN

Date: JUL.24,2020

Page: 1 of 7

Client name : GUANGZHOU JUNDA GLOVES CO., LTD

Client address : NO.38 HETINGFENGWEI INDUSTRIAL ZONE, RENHE TOWN,
BAIYUN DIST, GUANGZHOU, CHINA

Sample Description : DISPOSABLE NITRILE GLOVES

Lot No. : NOT PROVIDED

Lot Size : NOT PROVIDED

Sample Quantity : 500PCS

Manufacturer : GUANGZHOU JUNDA GLOVES CO., LTD

Manufacturer Date : 2020.3

Storage Condition : ROOM TEMPERATURE


As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

SGS Ref. No. : TAOHG2002652101

Sample Receiving Date : JUN.29,2020

Final Sample Submission Date : JUL.22,2020

Test Performing Date : JUN.29,2020 TO JUL.24,2020



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检验检测专用章
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Test Report

No.: QDHL2004003693MD_EN

Date: JUL.24,2020

Page: 2 of 7

Test Requested

1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)
2. 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)
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4, 4.5, 4.6)

Result

Pass
Pass
See Results

Note: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

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

Jessica Gao

Jessica Gao
Approved Signatory



Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)32071443, or email: CN.Doc@sgs.com



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Test Report

No.: QDHL2004003693MD_EN

Date: JUL.24,2020

Page: 3 of 7

Test Conducted:

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

Number of test sample	:	200 Pieces
Sample size	:	L
Number of non-conforming gloves	:	0

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

Note	:	1	Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:0. The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.
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2. BS EN 455-2:2015 Medical gloves for single use – Part 2: Requirements and testing for physical properties

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves: b)
Size	:	Examination/procedure gloves: L

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)

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Test Report

No.: QDHL2004003693MD_EN

Date: JUL.24,2020

Page: 4 of 7

Result 1: Dimensions

Size No.	Length (mm)	Width (mm)
1	245	105
2	245	106
3	245	105
4	245	105
5	244	105
6	244	104
7	245	104
8	243	105
9	245	105
10	240	105
11	241	106
12	245	104
13	243	106
Standard requirement	≥240	110±10
Median value	245	105

Result 2: Strength

Size: L			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	6.6	1	6.7
2	6.8	2	6.7
3	6.6	3	5.5
4	7.0	4	6.7
5	6.8	5	6.6
6	6.8	6	6.2
7	6.8	7	6.3
8	6.6	8	6.5
9	6.2	9	6.0
10	7.5	10	6.1
11	6.7	11	6.6
12	7.5	12	6.5
13	6.7	13	6.0
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	6.8	Median value	6.5



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Test Report

No.: QDHL2004003693MD_EN

Date: JUL.24,2020

Page: 5 of 7

3. BS EN 455-3:2015 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
Size	:	L

Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)
4.5	Proteins, leachable	See result 1
4.6	Labelling	Pass

Note	:	1	Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.06mg. (Requirement: ≤2mg per powder-free glove)
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Result 1: Proteins, leachable

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

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

Remark:

- 1) The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.
- 2) Labelling assessment was based on the information provided by the customer, excluding the verification of the authenticity of the content. SGS is not responsible for verifying the accuracy of the information provided by customers.

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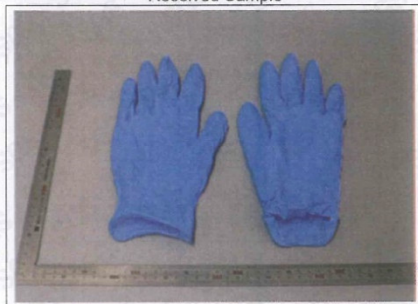
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Date: JUL.24,2020

Page: 6 of 7

Sample Photo:

Received Sample



Packaging-artwork



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Date: JUL.24,2020

Page: 7 of 7

Packaging-artwork

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基本属性: 材质: 优质丁腈橡胶 产地: 中国 长度: 9寸 (约230-240毫米) 颜色: 蓝色 包装: 100/200	Basic attributes: Material: high quality nitrile rubber Origin: China Length: 9 inches (about 230-240 mm) Color: Blue Packing: 100 PCS/box	<div style="border: 1px solid black; padding: 5px;"> 制造批号/lotch No.: ID 20200701 制造日期/Date of Manufacture: 2020-07 使用寿命/Service life: 三年/three years 生产产地/Production place: 中国/China ② 一次性使用/Disposable use </div>	
产品适用范围: 适用于医用检查、卫生防护	Scope of application: Suitable for medical examination and health protection		
注意事项: 1. 请选择合适的手套大小/厚度。 2. 打开包装, 仔细检查, 如发现任何破损, 请勿使用。 3. 使用尖锐器械时请防止利器戳破手套。	Notes: 1. Please choose the appropriate glove size. 2. Open the package and examine it carefully. If any damage is found, do not use it. 3. Please prevent the gloves from being cut when using sharp utensils.		
广州市俊达手套有限公司 GUANGZHOU JUNDA GLOVES CO.LTD	地址: 广州市白云区人和镇新丰里工业区内 Address: NO.30/Hongfeng Industrial Zone/Hongfeng, Baiyun District, Guangzhou 全国服务热线: 400-0016-389 传真: 020-36327836	 	

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End of Report



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Bestätigung



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