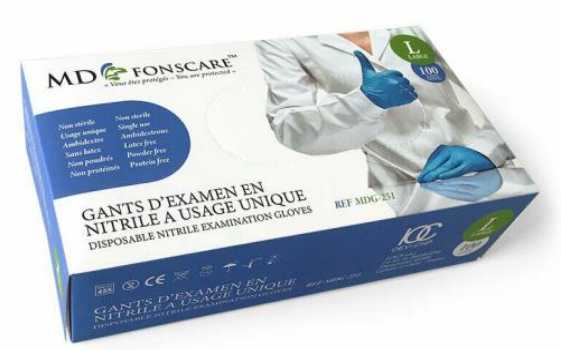
GUANTI IN NITRILE DISPOSITIVO MEDICO USO LAVORATORI E POPOLAZIONE

100 PZ CE



Guanti in nitrile, dispositivo medico

Guanti in nitrile. Ideali per uso comune e per uso ambulatoriale. Materiale resistente e elastico che permette massimo comfort. Comoda vestibilità grazie all ottima elasticità, si adatta facilmente alle forme di qualsiasi mano, lunga durata in condizioni di particolare stress. Confezioni 100 pz colore blu ambidestri.

Certificazione CE che ne permette la vendita come anche come DM eseguita da laboratorio accreditato SGS. L articolo risponde ai requisiti previsti dalla standard EN455-1-2-3, che lo classificano come DM.

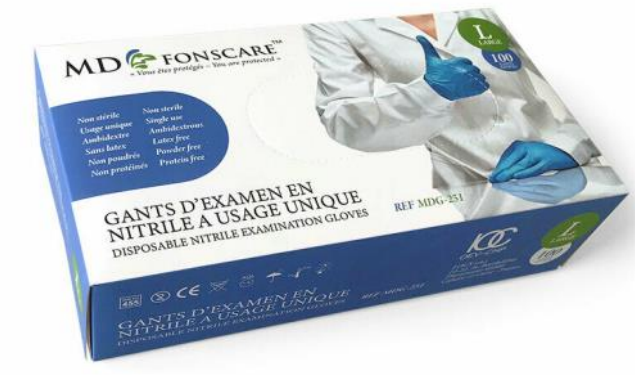
Per evitare reazioni allergiche i guanti sono privi di polvere. Inoltre assicurano un elevato livello di protezione del paziente e dell utilizzatore da reciproca contaminazione. (Test Report disponibili su richiesta)

Disponibili nelle taglie S-M-L-XL

DESCRIZIONE TECNICA	
MATERIALE	NITRILE DISPOSITIVO MEDICO
CONFEZIONE	100 PEZZI (peso ~400 gr cad)
MASTER CARTONE	10 CONF DA 100 PZ tot Kg 5

CONFORMITA'	
CE	

EN 455—EN 374
EC 1935



ANAGRAFICA	
COD. ART.	GUANIS/GUANIM/GUANIL/ GUANIXL
DESCRIZIONE PRODOTTO:	GUANTI NITRILE 100 PZ DM
DESCRIZIONE TECNICA	GUANTI NITRILE DISPOSITIVI MEDICI
CODICE A BARRE	In funzione della taglia
INNER	10 confezioni per taglia
MASTER	700 confezioni

TAGLIA SMALL	
COD. ART.	GUANIS
CODICE A BARRE	6905642864321
INNER	10 confezioni per taglia
MASTER	700 confezioni

TAGLIA MEDIUM	
COD. ART.	GUANIM
CODICE A BARRE	6905642864338
INNER	10 confezioni per taglia
MASTER	700 confezioni

TAGLIA LARGE	
COD. ART.	GUANIL
CODICE A BARRE	6905642864345
INNER	10 confezioni per taglia
MASTER	700 confezioni

TAGLIA XLARGE	
COD. ART.	GUANIXL
CODICE A BARRE	6905642864451
INNER	10 confezioni per taglia
MASTER	700 confezioni

EC Declaration of Conformity

Manufacturer:

SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD

ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99, JINJIHU AVENUE,SUZHOU INDUSTRIAL PARK,JIANGSU PROVINCE,CHINA

XINGYU XU
Tel: +86 15952427435
E-mail:1067704849@qq.com

whose single Authorized EU-Representative:

M/s CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

We, the manufacturer, herewith declare that the products

MEDICAL NITRILE INSPECTION GLOVES
XS
S
M
L
XL

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

SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99, JINJIHU AVENUE,SUZHOU INDUSTRIAL PARK,JIANGSU PROVINCE,CHINA

SUZHOU 2020.7.13
Place, date

XINGYU XU
Legally binding signature, Function

320594000279

中国认可
国际互认
检测
TESTING
CNAS L0604

scan to see the report

QDHL2105504184MD

Test Report

Report No.: QDHL2105504184MD

Sample Description:	DISPOSABLE POWDER FREE NITRILE GLOVES
Applicant:	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD
Test Type:	SUBMITTED BY CLIENT

Report No.: QDHL2105504184MD

Test Report

Sample information	Sample Description	DISPOSABLE POWDER FREE NITRILE GLOVES	Color	BLUE
	Received sample quantity/ Tested sample quantity	500PCS/ 231PCS	Size	L
	Lot No.	SYF-ST01	Lot Quantity	NOT PROVIDED
	Manufacture Date	2021-04-01	Expiration Date	5 YEARS
	Material	NITRILE		
	Manufacturer	NOT PROVIDED		
	Others	EXAMINATION GLOVES; POWDER-FREE GLOVES		
Client information	Applicant	SUZHOU SHIYIFANG BIOTECHNOLOGY CO., LTD		
	Applicant address	ROOM 302, BUILDING 12, NORTHWEST AREA, SUZHOU NANO CITY, NO.99,JINJIHU AVENUE, SUZHOU INDUSTRIAL PARK, JIANGSU PROVINCE, CHINA		

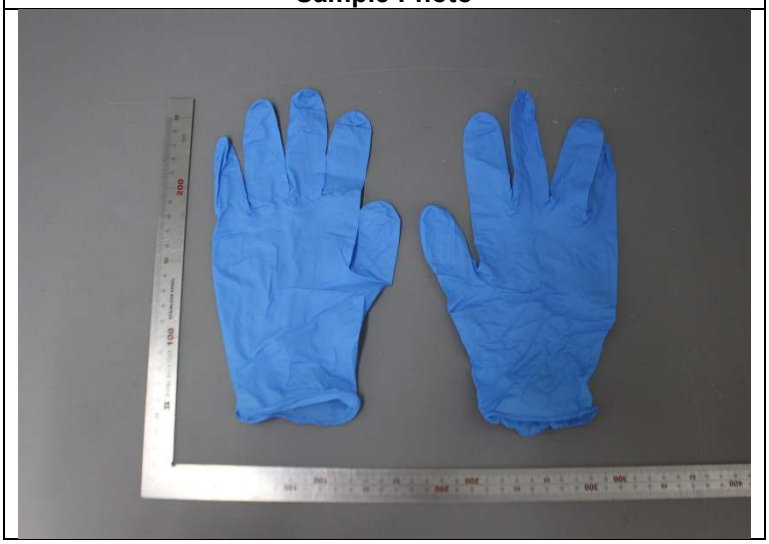
Report No.: QDHL2105504184MD

Test information	Sample Receiving Date	MAY.21,2021	Test Period Date	MAY.21,2021 TO JUN.08,2021
	Sample No.	QDHL2105504184MD	Test environment	Meet requirement
	Test items	Watertightness, Dimension (Length, Width), Tensile strength (Force at break, Force at break after challenge testing), Powder-free gloves		
	Testing Accordance	EN 455-1:2020 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes Clause 5.1 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 EN 455-3:2015 Medical Gloves for Single Use–Part 3: Requirements and Testing for Biological Evaluation clause 4.4		
Test conclusion	This report only provides the test results and individual judgment, conclusion please see follow pages. Issue date: JUN.08,2021			
Remark	/			

Approver: Jessica Co Auditor: Crystal Sun Compiler: Lillian Diao

Date: JUN.08,2021 Date: JUN.08,2021 Date: JUN.08,2021

Report No.: QDHL2105504184MD

Sample Photo


SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Report No.: QDHL2105504184MD

Test Results

Test Items		Unit	Test Method	Requirement		Test Result	Assessment
Watertightness		/	EN 455-1: 2020 Clause 5.1	Sample quantity: 200pcs AQL: 1.5 Ac: 7 Re: 8		Found: 0	Pass
Dimension	Length	mm	EN 455-2: 2015 Clause 4.2	Median value: L: ≥240	Sample quantity: 13pcs	See appendix 1 for details	Pass
	Width	mm	EN 455-2: 2015 Clause 4.3	Median value: L: 110±10			Pass
Tensile strength	Force at break	N	EN 455-2: 2015 Clause 5.2	Median value: b): ≥6.0	Sample quantity: 13pcs	See appendix 2 for details	Pass
	Force at break after challenge testing	N	EN 455-2: 2015 Clause 5.3	Median value: b): ≥6.0			Pass
Removable surface powder (Powder-free gloves)		mg	EN 455-3: 2015 Clause 5.2 EN ISO 21171: 2006 Method B	Sample quantity: 5pcs Average: ≤2		0.1	Pass

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Report No.: QDHL2105504184MD

Appendix 1: Dimension

Size	L	
No.	Length (mm)	Width (mm)
1	240	106
2	240	106
3	241	106
4	240	106
5	240	106
6	240	106
7	240	106
8	243	106
9	240	107
10	240	106
11	240	107
12	240	106
13	240	106
Standard requirement	≥240	110±10
Median value	240	106

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Report No.: QDHL2105504184MD

Appendix 2: Tensile Strength

Size: L			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	6.1	1	6.5
2	7.6	2	7.7
3	7.9	3	7.1
4	7.9	4	6.5
5	7.5	5	6.5
6	8.1	6	6.6
7	8.1	7	7.3
8	6.6	8	6.8
9	8.3	9	6.9
10	7.4	10	6.4
11	6.6	11	6.8
12	6.8	12	6.6
13	6.2	13	6.1
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	7.5	Median value	6.6

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

End of Report

SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, Shandong, China 266101 t (86-532) 68999888 www.sgsgroup.com.cn sgs.china@sgs.com

Statement

1. The report is considered invalidated in one or more of the following conditions: no approval signature; no testing seal of SGS; altered;a copy without the red testing seal of SGS.

2. Above information and sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

3. 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.

4. The test report cannot be reproduced in any way, except in full content, without prior approval in writing by the laboratory.

5. Should you have any queries or objection to the test report, please contact us whthin 15 days after receiving the report.

Address:
SGS Center, No.143, Zhuzhou Road, Laoshan District, Qingdao, China.

Tel: 0532-68999187 Zip: 266101
Fax: 0532-80991952

E-mail: Emily.Zhang@sgs.com

Issued to:

Suzhou SHIYIFANG Biotechnology Co Ltd
Room 302 Building 12, Nortwest Area
Suzhou Nano City, No.99 Jinjihu Avenue
Suzhou Industrial Park
Jiangsu Province
215000
China

Notified Body: 2777

SATRA customer number: P21098

EU Type-Examination Certificate

Certificate number: 2777/16527-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

SYF-ST01

Description:

Disposable Powder Free Nitrile Gloves

Colour: Blue

Sizes:

S/6, M/7, L/8, XL/9

Classification:

EN ISO 374-1:2016+A1:2018 /Type C	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium Hydroxide (K)	5	-23.4
30% Hydrogen Peroxide (P)	1	35.8
37% Formaldehyde (T)	5	13.6

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied**:**
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0307836/2104, CHT0305868/2049, CHM0308176/2105/JH/A, CHM0308176/2105/JH/B

Signed on behalf of SATRA:

Quincey Brown

Date first issued: 30/04/2021
Date of issue: 30/04/2021
Expiry date: 30/04/2026

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

Notified Body: 2777 SATRA customer number: P21207

EU Type-Examination Certificate

Certificate number: 2777/16527-02/E01-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

MDG-251

Description:

Disposable Powder Free Nitrile Gloves

Colour: Blue

Sizes:

S/6, M/7, L/8, XL/9

Classification:

EN ISO 374-1:2016+A1:2018 /Type C	Level	EN ISO 374-4:2019 Degradation %
40% Sodium Hydroxide (K)	5	-23.4
30% Hydrogen Peroxide (P)	1	35.8
37% Formaldehyde (T)	5	13.6

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0307836/2104, CHT0305868/2049, CHM0308176/2105/JH/A, CHM0308176/2105/JH/B

Signed on behalf of SATRA: Quincey Brown

Date of issue: 20/08/2021
Expiry date: 30/04/2026