



Guanti monouso da visita in nitrile

Non sterili - Ambidestri - Senza polvere - Senza Proteine - Senza Lattice



Guanti monouso da visita in nitrile

REF MDG-251



Caratteristiche

- Nonsterili
- Ambidestri
- Senza polvere
- Senza proteine
- Senza lattice

I simboli sulla scatola



Norme EN 455



Norme EN 374-5



Norme CE



Contatto alimentare
(EC1935/2004)



Monouso



Senza lattice

Altre norme :

- EN 374-2 / 4
- ISO 13485
- EN 21420 (ex EN 420)
- EN 16523-1 (ex 374-3)



AQL : 1.5



Istruzioni di conservazione



- Al riparo dalla luce
- Al riparo dall'umidità
- Temperatura +5° | +38°



Numero di Lotto

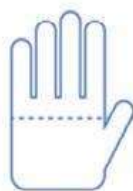


Fabbricazione



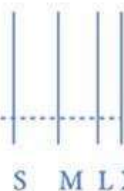
Data di scadenza

Indicatore di taglie



Définir sa taille en appliquant la main sur le repère de taille, sans prendre en compte le pouce (tolérance 2 à 5 mm)

The actual width must be based on the width of the ruler (tolerance allowed is about 2 to 5 mm)



Taglie Disponibili : S - M - L - XL

Fabbricante :

Suzhou SHIYIFANG Biotechnology Co., Ltd
Room 302, building 12, northwest area, Suzhou nano City, No.
99, Jinjihu Avenue, Suzhou Industrial Park, Jiangsu Province,
China

Dispositivi medicali

La norma EN 455

Regolamenta le prestazioni dei guanti da visita ad uso medicale

EC1935/2004 - Alimentaire

Materiali ed oggetti destinati ad entrare in contatto con derrate alimentari

EN 374 -2/4 - ISO 16523

Protezione contro i prodotti chimici:
Penetrazione - permeazione e degradazione

EN 374-5

Protezione contro i micro-organismi e virus

Attenzione: Certi simboli potrebbero non apparire sulle scatole in funzione dei lotti. Noi mettiamo a disposizione tutti i test a corredo delle norme.


Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

Dichiarazione di conformità




EC Declaration of Conformity

This is a declaration of conformity made According to Art .19 of Regulation (EU) 2017/745 on Medical Devices

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. Xin Cui Tel: +0512-68122111 Email: 83161161@qq.com	whose single Authorized EU-Representative: Name: StateLab GmbH Add:Friedrich-Ebert- Straße 7 58642 Iserlohn
---	--

Product Name: Disposable Powder Free Nitrile Gloves
Product type: S/M/L/XL
Product Classification: Class I , Non-sterile, No measuring function (MDR,Annex VIII, Rule 1)
Basic UDI : Not available yet

We hereby declare that above mentioned devices comply with (EU) MDR 2017 /745 and the following harmonized standards.
Executive standard: EN 455-1:2020, EN 455-2:2015,EN 455-3:2015.
meet the provisions of Directive2017/745(EU) which apply to them.
It bears the mark




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.

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 2021.6.15
Place, date

Cuixin General manager
Legally binding signature, Function



Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

- Certificazione CE

 	Issued to: Suzhou SHIYIFANG Biotechnology Co Ltd Room 302 Building 12, Northwest Area Suzhou Nano City, No.99 Jinjihu Avenue Suzhou Industrial Park Jiangsu Province 215000 China																		
Notified Body: 2777	SATRA customer number: P21098																		
<h3>EU Type-Examination Certificate</h3>																			
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: <table border="1"> <thead> <tr> <th>EN ISO 374-1:2016+A1:2018 /Type C</th> <th>Level</th> <th>EN ISO 374-4:2019 Degradation %</th> </tr> </thead> <tbody> <tr> <td>40% Sodium Hydroxide (K)</td> <td>5</td> <td>-23.4</td> </tr> <tr> <td>30% Hydrogen Peroxide (P)</td> <td>1</td> <td>35.8</td> </tr> <tr> <td>37% Formaldehyde (T)</td> <td>5</td> <td>13.6</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th>EN ISO 374-5:2016</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td>Protection against Bacteria and Fungi</td> <td>Pass</td> </tr> <tr> <td>Protection against Viruses</td> <td>Pass</td> </tr> </tbody> </table>	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	Pass	Protection against Bacteria and Fungi	Pass	Protection against Viruses	Pass
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	Pass																		
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																		

Page 1 of 2

SATRA Technology Europe Limited, Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.

Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

- Norma EN374-5

SATRA TECHNOLOGY
SATRA Technology Services (Dongguan) Ltd
Unit 110, Xuezhongyuan Garden, Xiang
Nanoheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22008822
Email: info@satratec.com

Customer details: Suzhou SHIYIFANG Biotechnology Co., Ltd. SATRA reference: CHT0305888 /2049
Room 302, building 12,
northwest area,
Suzhou nano City,
No.99, Jinghua Avenue,
Suzhou Industrial Park,
Jiangsu Province,
China

Your reference: Nitrile Gloves
Date of report: 23 December 2020
Samples received: 4 December 2020
Date(s) work carried out: 8-18 December 2020


TECHNICAL REPORT

Subject: EN ISO 374-5: 2016 viruses test on Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M

SATRA TECHNOLOGY TECHNICAL REPORT

WORK REQUESTED
Samples described as Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M were received by SATRA on 04 December 2020 for testing in accordance with EN ISO 374-5: 2016.

SAMPLE SUBMITTED



Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M

TESTING REQUESTED
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 16604: 2004 Procedure B)

CONCLUSION
The samples described as Disposable Powder Free Nitrile Gloves, Colour: Blue, Size: 7M were found to achieve the following result:
EN ISO 374-5: 2016 Clause 5.3 – Pass
Detailed results are included on the following page(s)

Suzhou SHIYIFANG Biotechnology Co., Ltd.
SATRA Reference: CHT0305888 /2049
Date: 23 December 2020

Signed: Adam Zhang
Technologist
China Testing

(Page 2 of 5)

Conditions of Issue:
This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.
A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.
Please note uncertainty of measurement has not been applied to the results in this report. SATRA uncertainty of measurement values are available on request.

Report signed by: Adam Zhang
Position: Technologist
Department: China testing

(Page 1 of 5)

Adam Zhang

Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

- Norma EN455

SGS

Test Report No.: QDHL2006005935MD_EN Date: JUL.09.2020 Page 2 of 5

Test Requested	Result
1. BS EN 455-1:2000 Medical Gloves for Single Use – Part 1: Requirements and Testing for Freedom from Holes (Clause 5.1)	Pass
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)	Pass
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4)	Pass

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

scan to see the report

QDHL2006005935MD

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed on the reverse, available on request or accessible at <http://www.sgs.com/our/terms-and-conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/our/terms-and-conditions.aspx#e-document-terms>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from asserting all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center, No. 143, Zhuoshou Road, Laoshan District, Qingdao, China 266701
T: (86-532) 68999888 F: (86-532) 80991855

7385972
www.sgs.com.cn
sgs.china@sgs.com

Member of the SGS Group (SGS SA)

La certificazione completa e originale è disponibile sul sito dei laboratori SGS



Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

EC 1935/2004

Alimentare

SGS

Test Report No. SHAHG2103905201 Date: 18 Mar 2021 Page 4 of 5

Simulant Used: 3% Acetic acid (W/V) aqueous solution
Test Condition: 40 °C 0.5 hr(s)

Test Item(s)	Max. Permissible Limit	Unit	Max. Limit	Test result
Migration times	-	-	-	First
Area/volume	-	dm ² /kg	-	6.0
Specific migration of Nitrosamines	0.01	mg/kg	0.01	ND
Specific migration of Nitrosatable substances	0.1	mg/kg	0.1	ND
Conclusion				PASS

Notes:

(1) Nitrosamines tested: N-nitrosodimethylamine (NDMA), N-nitrosodiethylamine (NDEA), N-nitrosodipropylamine (NDPA), N-nitrosodibutylamine (NDBA), N-nitrosopiperidine (NPIP), N-nitrosopyrrolidine (NPYR), N-nitrosomorpholine (NMOR), N-nitrosodibenzylamine (NDBzA), N-nitroso-N-methyl-N-phenylamine (NMPHA), N-nitroso-N-ethyl-N-phenylamine (NEPHA), N-nitrosodisononylamine (NDiNA) and N-Nitrosodisobutylamine (NDiBA)

(2) Test condition & simulant were specified by client.

Commission Implementing Regulation (EU) 2018/213 of 12 February 2018 amending Regulation (EU) 10/2011 of 14 January 2011-Bisphenol A

Test Method: With reference to Part II Section U2 of Testing Methods for Foodstuffs, implements, Containers and Packaging, Toys, Detergents, JETRO, Japan External Trade Organization, 2009 (Dichloromethane extraction by ultrasonic bath). Analysis was performed by HPLC-MS.

Test Item(s)	Limit	Unit	MDL	OT
Bisphenol-A	*	mg/kg	0.1	ND
Conclusion				PASS

Notes:
* = prohibited

scan to see the report



SHAHG2103905201

Guanti monouso da visita in nitrile

REF MDG-251



Le certificazioni e i test

374-4 et 16523-1



SGS

Test Report No.: QDHL2006005936MD_EN Date: JUL.16.2020 Page: 3 of 4

Test Conducted:

Test Items	Unit	Test Method	Test Result
Resistance to degradation by chemicals	-	EN ISO 374-4: 2019	Formaldehyde 37% DR1:32.8% DR2:31.0% DR3:29.4% DR:31.1% SD:1.70 There was no obvious change in the physical appearance of the material after chemical exposure
			Hydrogen peroxide 30% DR1:57.0% DR2:57.4% DR3:58.7% DR:57.7% SD:0.89 There was no obvious change in the physical appearance of the material after chemical exposure
			Sodium hydroxide 40% DR1: -27.8% DR2: -27.5% DR3: -33.5% DR: -29.6% SD:3.39 There was no obvious change in the physical appearance of the material after chemical exposure
Permeation by liquid chemical	min	EN ISO 16523-1: 2015	Formaldehyde 37% > 480 Level: 6 Refer To appendix 1
			Hydrogen peroxide 30% > 480 Level: 6 Refer To appendix 1
			Sodium hydroxide 40% > 480 Level: 6 Refer To appendix 1



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overall, available on request or accessible at <http://www.sgs.com/na/en/na-conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/na/en/na-conditions.aspx> and Conditions for e-Documents.aspx. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained herein reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to the Client and this document does not constitute part of a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

SGS Center No. 143, Zhushou Road, Luoshan District, Chongqing, China 288001

QD

7382534
www.sgs.com.cn

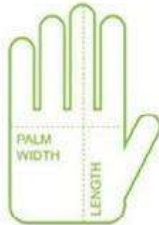
Guanti monouso da visita in nitrile

REF MDG-251



I guanti in dettaglio

SIZE	PALM WIDTH	LENGTH	WEIGHT
S	85±5mm	250±5mm	3.5g±5%
M	95±5mm	250±5mm	3.9g±5%
L	105±5mm	250±5mm	4.3g±5%
XL	115±5mm	250±5mm	4.7g±5%



FINGER TIP	PALM	WRIST
0.1mm	0.08mm	0.08mm

La scatola in dettaglio

Confezionamento

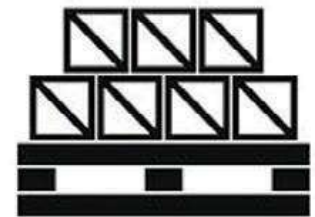
- Scatole
- Cartoni
- Pallet

Confezionamento

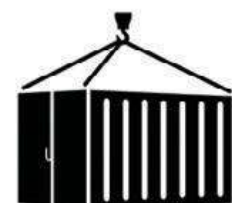
Scatola distributrice da 100 guanti



Cartoni da 10 scatole
cioè 1.000 guanti



70 cartoni per pallet
cioè 700 scatole
per pallet.



3 450 cartoni /
container

Ripartizione per taglie
S : 10% - M : 40% - L : 40% - XL : 10%



Guanti monouso da visita in nitrile

REF MDG-251



Qualità

- Controllo di produzione



Prelievo e test

Dei controlli casuali sono effettuati lungo la linea di produzione : dalla fabbricazione alla spedizione al fine di garantire la qualità dei prodotti.

