



## DECLARATION OF CONFORMITY

### Importer

S.A.S LOCX  
6 boulevard des Monts d'Or  
69580 Sathonay-Camp

### Manufacturing

Suzhou Shiyifang Biotechnology Co., Ltd  
Room 302, Building 12, Northwest area, Suzhou nano city, no. 99, Jinjihu Avenue,  
Suzhou Industrial Park, Jiangsu Province, China

**Designation and Reference**  
DISPOSABLE NITRILE EXAMINATION GLOVES  
REFERENCE : MDG-251

### Normes

Norme	Certification Organism	Issued	Report/Certificate Ref.
EN 455-1/2/3	SGS	2021-06-15	Declaration of conformity
EN 374-2:2019	SGS	2020-08-05	QDHL2007007117MD_EN
EN 374-1:2016+A1:2018	SATRA	2021-08-20	2777/16527-02/E01-01
EN 374-5:2016	SATRA	2020-12-23 08-20-21	CHT0305868 / 2049 2777/16527-02/E01-01
EN 16523-1 :2015	SGS	2020-07-16	QDHL2006005936MD_EN
EN 374-4 :2019	SGS SATRA	2020-07-16 2021-08-20 - 2026-04-30	QDHL2006005936MD_EN 2777/16527-02/E01-01
EC 1935/2004 VO (EU) 10/2011	SGS	2021-03-18	SHAHG2103905201
EN 21420:2020	SATRA	2021-08-20 - 2026-04-30	2777/16527-02/E01-01
ISO EN 13485:16	SATRA	2021-08-20 - 2026-04-30	2777/16527-02/E01-01

As well as ISO EN 13485:2016 (LOCX), COMMISSION REGULATION (EC) No 2023/2006.

LOCX, Président , Olivier Euvrard  
11/01/2022

  
**S.A.S LOCX**  
6 boulevard des Monts d'Or  
69580 Sathonay-Camp  
TVA FR43817697659  
SIRET 81769765900024  
tel: +33(0)4 37 65 20 20

# CE Dichiarazione di conformità

Il 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

## Il Mandatario

RAMY HEALTH S.R.L.

con sede in Sede Via San Gregorio, 55  
20124 – Milano (MI) Italy

Partita IVA: 12136420010

## Dichiara

che il prodotto: Guanti in Nitrile

Modello e codice: MD FONSCARE

Classe: I/ Cat III

Data di scadenza prodotto: 04/2025

Data di fabbricazione prodotto: 04/2021

Numero di serie:

È stato costruito rispettando le seguenti direttive e norme:

- Regolamento (UE) n.745/2017 Regolamento relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio
- Direttiva 2006/42/CE – Direttiva macchine
- Norma IEC 61882:2016 Metodo di analisi dei rischi secondo il metodo HAZOP
- Norma IEC 61511-1:2016 - Functional safety - Safety instrumented systems for the process industry sector - Part 1: Framework, definitions, system, hardware and application programming requirements
- EN 62366: 2008 – 01 Medical devices Application of usability engineering to medical devices Recepisce IEC 62366
- UNI CEI EN ISO 15223-1:2017 Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite – Parte 1: Requisiti generali
- UNI CEI conosciuta anche come direttiva sulla sicurezza generale dei prodotti
- EN 1041:2009 Informazioni fornite dal Fabbrikante con i dispositivi medici
- UNI CEI EN 14971:2012 Applicazione della gestione dei rischi a dispositivi medici
- Direttiva 2001/95/CE
- Test report No SHAHG2103905201
- Test report BS EN 455-1:20007 BS EN 455-2:2015/ BS EN 455:2015
- Test method EN 1186-9:2002/ EN 1186-2:2002
- Test method EN 13130-1:2004
- Test method EN ISO 374-4:2019/ EN ISO 16523-1:2015
- Regolamento (EC) No 1935/2004
- Regolamento (EU) 2018/213 DEL 12 febbraio 2018
- Report tecnico EN ISO 374-5:2016
- Report tecnico EN ISO 374-5:2016
- Test Protezione Virus No 20r007218 Laboratorio CNAS accreditato ISO 17025:2017 con ISO 16604:2004

Ed è quindi conforme alle direttive e normative vigenti.

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del Mandatario

Luogo: Milano

Data: 16/11/2021

Rev. 0

Firma Mandatario

**RAMY HEALTH SPA**  
Via San Gregorio 55  
20124 Milano (MI)  
P. IVA 12136420010



# 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

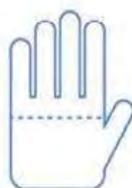


Fabbricazione



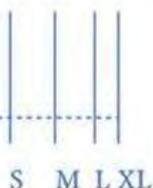
Data di scadenza

## 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



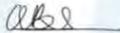
# Guanti monouso da visita in nitrile

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>																				
<b>Certificate number: 2777/16527-01/E00-00</b>																				
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.																				
<b>Product reference:</b> SYF-ST01	<b>Description:</b> Disposable Powder Free Nitrile Gloves  Colour: Blue																			
<b>Sizes:</b> S/6, M/7, L/8, XL/9	<b>Classification:</b> <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 %																		
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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																		

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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 Services (Dongguan) Ltd  
Unit 110, Xingzhong Garden, Xingzhong  
Nanzheng District, Dongguan City  
Guangdong Province, China  
Tel: +86 (0) 769 22008022  
email: info@satraf.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



### 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)

#### 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*

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

Signed: *Adam Zhang*  
Technologist  
China Testing

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# 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

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



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Member of the SGS Group (SGS SA)

# 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.	Test result
Migration times:	-	-	-	First
Area/volume	-	dm <sup>2</sup> /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 (NPNR), 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, Impurities, 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



## 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

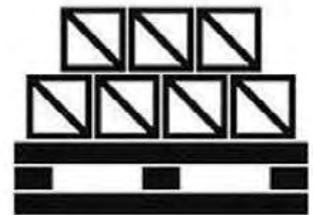
- Scatole
- Cartoni
- Pallet

## Confezionamento

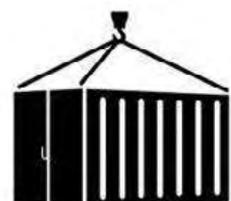
Scatola distributrice da 100 guanti



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.

