



## 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<br>08-20-21                   | CHT0305868 / 2049<br>2777/16527-02/E01-01   |
| EN 16523-1 :2015                | SGS                    | 2020-07-16                               | QDHL2006005936MD_EN                         |
| EN 374-4 :2019                  | SGS<br>SATRA           | 2020-07-16<br>2021-08-20 -<br>2026-04-30 | QDHL2006005936MD_EN<br>2777/16527-02/E01-01 |
| EC 1935/2004<br>VO (EU) 10/2011 | SGS                    | 2021-03-18                               | SHAHG2103905201                             |
| EN 21420:2020                   | SATRA                  | 2021-08-20 -<br>2026-04-30               | 2777/16527-02/E01-01                        |
| ISO EN 13485:16                 | SATRA                  | 2021-08-20 -<br>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

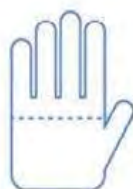


Fabbricazione



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*

|   |  |
|---|--|
| <b>Manufacturer:</b><br><br>Suzhou SHIYIFANG Biotechnology Co.,Ltd.<br>Room 302,building 12,northwest area,Suzhou nano<br>City,No.99,Jinjihu Avenue,Suzhou Industrial Park,Jiangsu<br>Province,China.<br>Xin Cui<br>Tel: +0512-68122111<br>Email: 83161161@qq.com | <b>whose single Authorized EU-Representative:</b><br><br>Name: StateLab GmbH<br>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




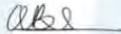
# Guanti monouso da visita in nitrile

REF MDG-251



## Le certificazioni e i test

- Certificazione CE

|   |   | Issued to: Suzhou SHIYIFANG Biotechnology Co Ltd<br>Room 302 Building 12, Northwest Area<br>Suzhou Nano City, No.99 Jinjihu Avenue<br>Suzhou Industrial Park<br>Jiangsu Province<br>215000<br>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:<br>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><br>SYF-ST01  | <b>Description:</b><br>Disposable Powder Free Nitrile Gloves<br><br>Colour: Blue  |   |       |                                 |                          |   |       |                           |   |      |                      |   |      |  |  |
| <b>Sizes:</b><br>S/6, M/7, L/8, XL/9   | <b>Classification:</b><br><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> | 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 374-1:2016+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  |       |                                 |                          |   |       |                           |   |      |                      |   |      |  |  |
|  |   | <b>EN ISO 374-5:2016</b><br>Protection against Bacteria and Fungi Pass<br>Protection against Viruses Pass   |       |                                 |                          |   |       |                           |   |      |                      |   |      |  |  |
| Standards/Technical specifications applied:<br>EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016   |   |   |       |                                 |                          |   |       |                           |   |      |                      |   |      |  |  |
| Technical reports/Approval documents:<br>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<br>Date of issue: 30/04/2021<br>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 Services (Dongguan) Ltd  
Unit 110, Xingzhong Garden, Xingzhong  
Nanzheng District, Dongguan City  
Guangdong Province, China  
Tel: +86 (0) 769 22008028  
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

(Page 2 of 5)

# 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



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QDHL2006005935MD

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QD

7385972

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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 (NPIR), 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

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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%<br>DR1:32.8%<br>DR2:31.0%<br>DR3:29.4%<br>DR:31.1%<br>SD:1.70<br>There was no obvious change in the physical appearance of the material after chemical exposure             |
|  |      |                      | Hydrogen peroxide 30%<br>DR1:57.0%<br>DR2:57.4%<br>DR3:58.7%<br>DR:57.7%<br>SD:0.89<br>There was no obvious change in the physical appearance of the material after chemical exposure        |
|  |      |                      | Sodium hydroxide 40%<br>DR1: -27.8%<br>DR2: -27.5%<br>DR3: -33.5%<br>DR: -29.6%<br>SD:3.39<br>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%<br>> 480 Level: 6 Refer To appendix 1   |
|  |      |                      | Hydrogen peroxide 30%<br>> 480 Level: 6 Refer To appendix 1  |
|  |      |                      | Sodium hydroxide 40%<br>> 480 Level: 6 Refer To appendix 1   |

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SGS Center No. 143, Zhushou Road, Luoshan District, Chiyao, China 206901

QD

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# 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

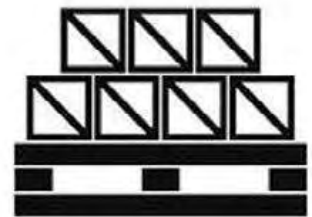
- Scatole
- Cartoni
- Pallet

## Confezionamento

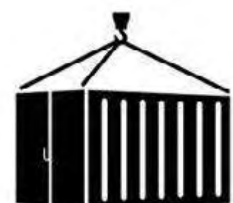
Scatola distributrice da 100 guanti



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.

