Sisma | SAMURAI COTONEVE FARMACOTONE LOGEX
Rendiamo cose Semplici Uniche

Spett.le Dott.ssa Orsini Claudia

Bollate, 01/06/2021

**OGGETTO – Fornitura guanti monouso in Nitrile: DM and DPI cat. III**

Con riferimento alla fornitura in oggetto inviamo in allegato alla presente

1. Dichiarazione di Conformità
    a. Logex (3476LX) DM e DPI cat III
    b. Kichy DM
2. Certificato marcatura CE Organismo notificato Satra 2777
    a. Logex (3476 LX) DPI Cat III
3. Registrazione portale Ministero della Salute
    a. Kichy: 2088887
    b. Logex (3476 LX): 2038717

*I guanti sono a marchio Logex hanno come fabbricante Ningbo a cui fanno riferimento i relativi certificati.*

Sisma
Sede legale in Mantova (Italy) - 46100 - loc. Valdaro, Via Stoppani, 2
P. IVA e C.F. IT 01271740209 - PEC: sisma.spa@legalmail.it
Stabilimento di Bollate (MI) - 20021 loc. Ospiate, via Galileo Ferraris, 18
Codice SDI: 5MQR541

# CE EU DECLARATION OF CONFORMITY CE

## *Ningbo Tianshun Rubber Products Co. Ltd.*

**Declaration Number:** 20200312-0001

**The manufacturer:** Ningbo Tianshun Rubber Products Co. Ltd.
Yushan Industrial Zone, Sanqishi Yuyao, Ningbo, Zhejiang, China.

**EU-Representative:** Luxus Lebenswelt GmbH
Kochstr.1, 47877,Willich,Germany
DIMID: DE/0000047791
E-mail: info.m@luxuslw.de

**Declare that the product:** Nitrile Disposable Examination Gloves
**Latex Disposable Examination Gloves**

- made of NBR(Nitrile) and NR(Latex)
- class I
- non-sterile
- colors: blue, white
- sizes: XS, S, M, L, XL

Is conformal to the following directives and standards:

**93/42/EEC - Medical devices**

**Harmonised Standards**

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

**EN 455-2:2009 +A2:2013** Medical gloves for single use - Part 2: Requirements and testing for physical properties

**EN 455-3:2006** Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.

This declaration of conformity is issued under the exclusive responsibility of the manufacturer

*Ningbo, China, 2020-03-12*

*Ningbo Tianshun Rubber Products Co. Ltd.*
*CHEN Xuefeng*
*Managing Director*

CHEN

# EU DECLARATION OF CONFORMITY

## *Ningbo Tianshun Rubber Products Co. Ltd.*

**Declaration Number:** 20210517-0001

**The manufacturer:** Ningbo Tianshun Rubber Products Co. Ltd.
Yushan Industrial Zone, Sanqishi Yuyao, Ningbo, Zhejiang, China

**Certificate issued by:** SATRA Technology Europe Limited
Brucetown Business Park.
Chonee D15YN2P
Republic of Ireland

**Certificate Number:** 2777/16611-01/E00-00

**Declare that the product:** Disposable Nitrile Examination Gloves

- Made of NBR(Nitrile)
- Category III
- Non-Sterile
- Colors: Clear,Blue
- Size: XS,S,M,L,XL

Is conformal to the following directives and standards:

**PPE (EU) 2016/425 - PPE devices**

**Harmonised Standards**

**EN 16523-1:2015 - Test report no:7191238363-EEC20-WBH (by TÜV)**
**EN 420:2003 - Test report no:7191238363-EEC20-WBH (by TÜV)**
**EN 374-1: 2016 - Test report no:7191238363-EEC20-WBH (by TÜV)**
**EN 374-2:2014 - Test report no:7191238363-EEC20-WBH (by TÜV)**
**EN 374-5:2016 - Test report no:721654734 (by TÜV)**
**EN ISO 374-2:2019 - Test report no:CHT0310379 2111 (by SATRA)**
**EN ISO 21420:2020 (PAHs) - Test report no:CHT0309604 /2019 (by SATRA)**
**EN ISO 374-4:2019 - Test report no:CHM0310637/2112/EN/B (by SATRA)**

This declaration of conformity is issued under the exclusive responsibility of the manufacturer

*NINGBO CHINA 2021-5-17*

*Ningbo Tianshun Rubber Products Co. Ltd.*

*CHEN Xuefeng*
*Managing Director*

CHEN

# CERTIFICATES

## Declaration of Conformity


**KICHY VIETNAM CO., LTD**

Office Address: Office No. 02, 8th floor, Pearl Plaza Building, No 561A Dien Bien Phu Street, Binh Thanh District, Ho Chi Minh City, 700000, Vietnam.
Manufacturer Address: Hamlet 3, Long An Commune, Long Thanh District, Dong Nai Province, 810000, Vietnam.
Tel: (+84) 28 6600 5658
Email: minhtamsouth@kichyvn.com; Website: www.kichyvn.com


### EC DECLARATION OF CONFORMITY

(Based on MDD 93/42/EEC as amended by 2007/47/EC for Medical Devices)

| | | |
|---|---|---|
| Name of the Company | : | **KICHY VIETNAM CO. LTD.** |
| Manufacturer Address | : | Hamlet 3, Long An commune, Long Thanh District, Dong Nai Province, 810000, Vietnam. |
| Corporate Office Address | : | Office No. 02, 8th floor, Pearl Plaza Building, No 561A Dien Bien Phu Street, Binh Thanh District, Ho Chi Minh City, 700000, Vietnam. |
| Product Name | : | **Nitrile Examination Glove** |
| Brand Name | : | **KICHY** |
| Classification and Justification | : | As per annexure IX of MDD 93/42/EEC, as amended by 2007/47/EC section 1.1 Rule 1 it's a Class I Medical Device. All non-invasive devices are in Class I. |
| Authorized Representative Name and Address | : | **Europecert**<br>Alsstr. 97, 41063 Mönchengladbach, Germany<br>support@europecert.eu |

We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of Annex VII of MDD 93/42/EEC as amended by 2007/47/EC for Medical Devices. *This declaration is based on the following*

a) EN 455-3:2015, EN 455-1:2000, EN 455-2:2015, EN ISO 14971:2012, EN ISO 13485:2016, EN ISO 15223-1:2016, EN 1041:2008.
b) Technical File ID: KVCL-MD-01/R1

| | | |
|---|---|---|
| Manufacturer | : | KICHY VIETNAM CO. LTD. |
| Name & Designation | : | Mr. Dong Hoang Nam, Director |
| Signature | : | KICHY VIỆT NAM |
| Date | : | 25th November 2020 |

Issued to:

Ningbo Tianshun Rubber Products Co., Ltd
Yunshan Industrial Zone
Sanqishi Yuyao
Ningbo City
Zhejiang
China

Notified Body: 2777

SATRA customer number: P21003

# EU Type-Examination Certificate

## Certificate number: 2777/16611-01/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:**

TS9B1300

**Description:**

Disposable Nitrile Examination Gloves.

Colour: Clear

**Sizes:**

M(7)

**Classification:**

| EN ISO 374-1:2016+A1:2018 /Type C | Level | EN ISO 374-4:2019 Degradation % |
|---|---|---|
| 40% Sodium Hydroxide (K) | 6 | -31.2 |
| 30% Hydrogen peroxide (P) | 1 | 34.2 |
| 37% Formaldehyde (T) | 6 | -3.8 |

| 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: CHT0310379/2111, CHT0309604/2109, CHM0310637/2112/EN/A, CHM0310637/2112/EN/B
TUV: 721654734

Signed on behalf of SATRA: Geoff Graham

**Date first issued: 16/05/2021**
**Date of issue: 16/05/2021**
**Expiry date: 16/05/2026**

# 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.

Ministero della Salute

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## Elenco dei dispositivi medici

**Criteri di ricerca:**
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **2088887**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

### Elenco dispositivi individuati

Dati aggiornati al:31/05/2021

| DISPOSITIVO MEDICO/ASSEMBLATO | | | | | | | | | FABBRICANTE/ASSEMBLATORE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TIPOLOGIA DISPOSITIVO | IDENTIFICATIVO DI REGISTRAZIONE BD/RDM | ISCRITTO AL REPERTORIO | CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE | NOME COMMERCIALE E MODELLO | CND | CLASSE CE | DATA PRIMA PUBBLICAZIONE | DATA FINE IMMISSIONE IN COMMERCIO | RUOLO AZIENDA | DENOMINAZIONE | CODICE FISCALE | PARTITA IVA/VAT NUMBER | NAZIONE |
| Dispositivo | 2088887 | N | 3616LXS 3616LXM 3616LXL 3617LXS 3617LXM 3617LXL 3621M 3621L 3621XL | GUANTI MONOUSO IN NITRILE | T010199 - GUANTI CHIRURGICI - ALTRI | I - Classe I non sterile e senza funzioni di misura | 08/04/2021 | | FABBRICANTE | KICHY VIETNAM CO., LTD | | | VN |
| | | | | | | | | | MANDATARIO | EUROPECERT | | DE307906781 | DE |

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Ministero della Salute

Stampa | Scarica il dataset

## Elenco dei dispositivi medici

**Criteri di ricerca:**
Denominazione fabbricante:
Codice fiscale fabbricante:
Partita IVA / VAT number fabbricante:
Codice nazione fabbricante:
Denominazione mandatario:
Codice fiscale mandatario:
Partita IVA / VAT number mandatario:
Codice nazione mandatario:
Tipologia dispositivo:
Identificativo di registrazione attribuito dal sistema BD/RDM: **2088887**
Codice attribuito dal fabbricante:
Nome commerciale e modello:
Classificazione CND:
Descrizione CND:
Classe CE (valida solo per dispositivi medici di classe, impiantabili attivi e IVD):

### Elenco dispositivi individuati

Dati aggiornati al:31/05/2021

| DISPOSITIVO MEDICO/ASSEMBLATO | | | | | | | | | FABBRICANTE/ASSEMBLATORE | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| TIPOLOGIA DISPOSITIVO | IDENTIFICATIVO DI REGISTRAZIONE BD/RDM | ISCRITTO AL REPERTORIO | CODICE ATTRIBUITO DAL FABBRICANTE/ASSEMBLATORE | NOME COMMERCIALE E MODELLO | CND | CLASSE CE | DATA PRIMA PUBBLICAZIONE | DATA FINE IMMISSIONE IN COMMERCIO | RUOLO AZIENDA | DENOMINAZIONE | CODICE FISCALE | PARTITA IVA/VAT NUMBER | NAZIONE |
| Dispositivo | 2088887 | N | 3616LXS 3616LXM 3616LXL 3617LXS 3617LXM 3617LXL 3621M 3621L 3621XL | GUANTI MONOUSO IN NITRILE | T010199 - GUANTI CHIRURGICI - ALTRI | I - Classe I non sterile e senza funzioni di misura | 08/04/2021 | | FABBRICANTE | KICHY VIETNAM CO., LTD | | | VN |
| | | | | | | | | | MANDATARIO | EUROPECERT | | DE307906781 | DE |

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