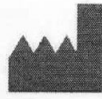


# EU DECLARATION OF CONFORMITY

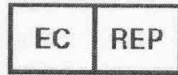
Doc No.: D-MDR-09/08-A01

## Identification of the Legal Manufacturer & Address



: Zibo Blue Sail Innovation Co., Ltd  
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,  
Zibo, Shandong 255414 China

## European Authorized Representative



: Lotus NL B.V.  
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,  
Netherlands  
: Email: [peter@loutsnl.com](mailto:peter@loutsnl.com)

## Basic UDI-DI

: **697521920EM0102156286CH**

## Product & Identification

: **Disposable Long Cuff Nitrile Examination Gloves, Powder Free**

## Intended purpose of the product:

The Disposable Nitrile Examination Gloves is a disposable product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

## GMDN code and product:

: **56286 Nitrile examination/treatment glove, non-powdered, non-sterile**

## EMDN code:

: **T01020204 GUANTI NON CHIRURGICI IN NITRILE  
EXAMINATION / TREATMENT GLOVES, NITRILE**

## Manufacturer SRN Number:

: CN-MF-000023103

## REP SRN Number:

: NL-AR-000000121

## Risk Classification:

: Class 1, Non-sterile, no measuring function and not surgical instrument

We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

## Conformity Assessment Procedure

: Article 52(7) and  
: Annex VIII, 4.1 Rule 1, Non-invasive device, and/or  
: 5.1 intended for transient use, Rule 5 of invasive device.

## Conformity Route

: Self-Declaration

## Relevant Harmonized Standards:

: EN ISO13485:2016  
: EN 455-1: 2020+A1:2022, EN455-2:2015, EN455-3:2015, EN455-4:2009

## EN 455 Standard Test Report

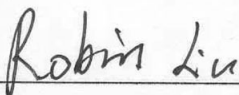
7191290097-EEC22-WBH\_CR1

## Quality System Certificate

: Certificate No.Q5 062837 0012 Rev.04  
: Certificate Body: TUV SUD Product Service GmbH  
: Issued Date: 04 Aug 2022 Valid Date: 31 Jul 2025

## Identification of the person authorized to sign on behalf of the Legal Manufacturer:

: Signed by:



: Print Name: Robin Liu  
: Title: Quality Director  
: Place: Zibo, Shandong, China

: Date: 23 Sep 2022

# EU DECLARATION OF CONFORMITY

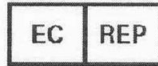
Doc No.: D-MDR-09/08-A01

**Identification of the Legal  
Manufacturer & Address**



: Zibo Blue Sail Innovation Co., Ltd  
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,  
Zibo, Shandong 255414 China

**European Authorized  
Representative**



: Lotus NL B.V.  
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,  
Netherlands  
: Email: [peter@loutsnl.com](mailto:peter@loutsnl.com)

**Basic UDI-DI**

: **697521920EM0102156286CH**

**Product & Identification**

: **Disposable Nitrile Examination Gloves, Powder Free**

**Intended purpose of the  
product:**

The Disposable Nitrile Examination Gloves is a disposable product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

**GMDN code and product:**

: **56286 Nitrile examination/treatment glove, non-powdered, non-sterile**

**EMDN code:**

: **T01020204 GUANTI NON CHIRURGICI IN NITRILE  
EXAMINATION / TREATMENT GLOVES, NITRILE**

**Manufacturer SRN Number:**

: CN-MF-000023103

**REP SRN Number:**

: NL-AR-000000121

**Risk Classification:**

: Class 1, Non-sterile, no measuring function and not surgical instrument

**We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.**

**Conformity Assessment  
Procedure**

: Article 52(7) and  
: Annex VIII, 4.1 Rule 1, Non-invasive device, and/or  
: 5.1 intended for transient use, Rule 5 of invasive device.

**Conformity Route**

: Self-Declaration

**Relevant Harmonized  
Standards:**

: EN ISO13485:2016  
: EN 455-1: 2020, EN455-2:2015, EN455-3:2015, EN455-4:2009

**EN 455 Standard Test Report**

7191273970-EEC22-01-WBH  
7191273970-EEC22-02-WBH  
7191273970-EEC22-03-WBH  
7191273970-EEC22-04-WBH  
7191294702-EEC22-WBH

**Quality System Certificate**

: Report No. BJ22092401  
: Certificate Body: TUV SUD Product Service GmbH  
: Issued Date: 04 Aug 2022 Valid Date: 31 Jul 2025  
: Signed by:

**Identification of the person  
authorized to sign on behalf of  
the Legal Manufacturer:**

: Print Name: Robin Liu  
: Title: Quality Director  
: Place: Zibo, Shandong, China  
: Date: 25 Nov 2022