# 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**

EC REP

:Lotus NL B.V.

: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

:Email: 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:

Robin Liu

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

:Date: 23 Sep 2022

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**Product & Identification** : **Disposable Nitrile Examination Gloves, Powder Free**

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**GMDN code and product:** : **56286 Nitrile examination/treatment glove, non-powdered, non-sterile**

**EMDN code:** : **T01020204 GUANTI NON CHIRURGICI IN NITRILE**
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**REP SRN Number:** : NL-AR-000000121

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: 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

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

Robin Liu

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

:Date: 25 Nov 2022