

# EU DECLARATION OF CONFORMITY

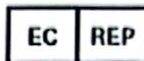
Doc No.: BD-MDR-01/10-A02

**Identification of the Legal  
Manufacturer & Address**



: Zibo Blue Sail Innovation Co., Ltd  
: SRN Number: CN-MF-000023103  
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,  
Zibo, Shandong 255414 China

**European Authorized  
Representative**



: Lotus NL B.V.  
: SRN Number: NL-AR-000000121  
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,  
Netherlands  
: Email: [peter@lotusnl.com](mailto:peter@lotusnl.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

**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  
: EN455-1:2020/A1:2022, EN455-2:2015, EN455-3:2023

**EN 455 Standard Test Report**

: 70.418.24.022.05A-00  
70.418.24.022.05B-00  
70.418.24.022.05C-00  
70.418.24.022.05D-00  
70.418.24.022.05E-00

**Quality System Certificate**

: Certificate No. Q5 062837 0012 Rev.05  
: Report No. BJ23092401  
: Certificate Body: TUV SUD Product Service GmbH  
: Issued Date: 27 Jun 2023 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: Shandong, China  
: Date: 20 Jun 2024