

# EU DECLARATION OF CONFORMITY

Doc No.: BD-MDR-01/10-A04

**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: [info@lotusnl.com](mailto:info@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**

: ISO 13485:2016  
: EN 455-1:2020/A2:2024, EN 455-2:2024, EN 455-3:2023

**Type 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.06  
: Report No. BJ25092401  
: Certificate Body: TÜV SÜD Product Service GmbH  
: Issued Date: 01 Aug 2025 Valid Date: 31 Jul 2028

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

: Signed by:

: Print Name: Robin Liu  
: Title: Quality Director  
: Location: Shandong, China  
: Date: 01 Aug 2025