

EU DECLARATION OF CONFORMITY

Doc No.: BD-MDR-01/10-A05

**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

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-antimicrobial

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 51 and Annex VIII, CHAPTER I 1.2 intended for short term use and CHAPTER III 5.1 Rule 5 of invasive device

Conformity Assessment Route

: Self-Declaration

Relevant Harmonized Standards

: ISO 13485:2016
: EN 455-1:2020/A2:2024, EN 455-2:2024, EN 455-3:2023
: 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
70.418.25.065.01A-00
70.418.25.065.01B-00
70.418.25.065.01C-00
70.418.25.065.01D-00
70.418.25.065.01E-00

Type Test Report

: Certificate No. Q5 062837 0012 Rev.06

Quality System Certificate

: Report No. BJ25092401

: Certificate Body: TÜV SÜD Product Service GmbH

: Issued Date: 01 Aug 2025 Valid Date: 31 Jul 2028

: Signed by:

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

: Print Name: Robin Liu

: Title: Quality Director

: Location: Shandong, China

: Date: 16 Feb 2026