

EU DECLARATION OF CONFORMITY

Doc No.: BD-MDR-02/10-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

Basic UDI-DI

: 697521920EM0101147176BL, Powder Free
: 697521920EM0101247177C3, Powdered

Product & Identification

: Disposable Vinyl Examination Gloves, Powder Free
: Disposable Vinyl Examination Gloves, Powdered

Intended purpose of the product

The Disposable Vinyl Patient 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

: 47176 Vinyl examination/treatment glove, non-powdered
: 47177 Vinyl examination/treatment glove, powdered

EMDN code

: T01020201 GUANTI NON CHIRURGICI IN VINILE
: EXAMINATION / TREATMENT GLOVES, VINYL

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

Powder Free : 70.418.23.034.06A-00
70.418.23.034.06B-00
70.418.23.034.06C-00
70.418.23.034.06D-00
70.418.23.034.06E-00
Powdered: 70.418.23.034.07-00

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