

EU DECLARATION OF CONFORMITY

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



: Lotus NL B.V.
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,
Netherlands
: Email: peter@louisnl.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**

SRN Number:

: CN-MF-000023103

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, EN455-2:2015, EN455-3:2015

EN 455 Standard Test Report

Powder Free :
7191292525-EEC22-01-WBH
7191292525-EEC22-02-WBH
7191271742-EEC21-02-WBH
7191271742-EEC21-03-WBH
7191271742-EEC21-04-WBH
Powdered:
7191271742-EEC21-01-WBH

Quality System Certificate

: Report No. BJ22092401
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 04 Aug 2022 Valid Date: 31 Jul 2025
: Signed by:

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

: Print Name: Robin Liu
: Title: Quality Director
: Place: Shandong, China
: Date: Mar 10 2023