

EU DECLARATION OF CONFORMITY

Doc No.: DD-MDR-01/10-A03

**Identification of the Legal
Manufacturer & Address**



: Zibo Blue Sail Health Technology Co., Ltd
: SRN Number:CN-MF-000023102
: No.1888 Honghua Road,High Technical Area,
Zibo, Shandong 255400 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

: 697521922EM0102156286F3

Reference Product Code

BS0102016, BS0102017,BS0102018, BS0102019,BS0102020

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

: **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

EN 455 Standard Test Report

: 70.418.24.022.08A-00
70.418.24.022.08B-00
70.418.24.022.08C-00
70.418.24.022.08D-00
70.418.24.022.08E-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:**

Robin Liu

: Print Name: Robin Liu
: Title: Quality Director
: Place: Shandong, China
: Date: 25 Mar 2025