

EU DECLARATION OF CONFORMITY

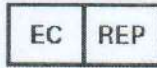
Doc No.: D-MDR-01/08-A01

**Identification of the Legal
Manufacturer & Address**



: Zibo Blue Sail Health Technology Co., Ltd
: No.1888 Honghua Road,High Technical Area,
Zibo, Shandong 255400 China

**European Authorized
Representative**



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

Basic UDI-DI

: 697521922EM0102156286F3

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**

Manufacturer SRN Number:

: CN-MF-000023102

REP SRN Number

: NL-AR-00:0000121

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 455-1:2020, EN455-2:2015, EN455-3:2015 , EN455-4:2009
: EN 1041:2008, EN 15223-1:2016, ISO 14971:2019
: ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2013

EN 455 Standard Test Report

: 7191273967-EEC22-01-WBH
: 7191273967-EEC22-02-WBH
: 7191273967-EEC22-03-WBH
: 7191273967-EEC22-04-WBH

Quality System Certificate

: Certificate No. Q5 062837 0012 Rev.04
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 11 Aug 2022 Valid Date: 31 Jul 2025

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

: Signed by:

: Print Name: Robin Liu
: Title: Quality Director
: Place of Issue: Zibo, Shandong, China
: Date: 18 Nov 2022