

EU DECLARATION OF CONFORMITY

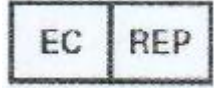
Doc No.. D-MDR-01/08-A01

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@lotusnl.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

: Annex VIII, 4.1 Rule 1, Non-invasive device, and/or
5.1 intended for transient use, Rule 5 of invasive device
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 II and III
: Self-Declaration

Conformity Route

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