

EU DECLARATION OF CONFORMITY

Doc No.: D-MDR-02/08-C00

Identification of the Legal
Manufacturer & Address



: Blue Sail Medical 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@loutsni.com

Basic UDI-DI

: 69332655MD010256286TC

Product & Identification

: Disposable Nitrile Examination Gloves, Powder Free

Intended purpose of the
product:

: The Disposable Nitrile 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:

: 56286 Nitrile examination/treatment glove, non-powdered, non-sterile

SRN Number:

: CN-MF-000001139

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: 2000, EN455-2:2015, EN455-3:2015

EN 455 Standard Test Report

1. 7191233436-EEC20/01-WBH
2. 7191233436-EEC20/02-WBH
3. 7191233436-EEC20/03-WBH
4. 7191233436-EEC20/04-WBH
5. 7191233436-EEC20/05-WBH

Quality System Certificate

: Certificate No: Q5 062837 0012 Rev. 02
: Certificate Body: TUV SUD Product Service GmbH
: Issued Date: 31 Jul 2022

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

: Signed by:

: Print Name: Robin Liu
: Title: Quality Director
: Place: Shandong, China
: Date: 23 Feb 2021