

# EU DECLARATION OF CONFORMITY

Doc No.: F-MDR-02/08-E01

Identification of the Legal  
Manufacturer & Address

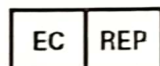


: Blue Sail Medical Co., Ltd  
: No. 21 Qingtian Road, Qilu Chemical Industrial Park,  
Zibo, Shandong 255414 China

Manufacturer SRN Number:

CN-MF-000001139

European Authorized  
Representative



: Lotus NL B.V.  
: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague,  
Netherlands Email: [peter@lotusnl.com](mailto:peter@lotusnl.com)

REP SRN Number:

NL-AR-000000121

Basic UDI-DI

69332655EM01021562864B

Product & Identification

**Disposable Nitrile Examination Gloves, Powder Free**

Ref: 942085;942086;942087;942088;942089

**Peha-soft® Nitrile Blue Disposable Nitrile Examination Gloves, Powder Free** Ref: 942011; 942012; 942013; 942014; 942015

Intended purpose of the  
product:

Disposable Nitrile Examination Gloves, Powder Free and The Peha-soft® Nitrile Blue Disposable Nitrile Examination Gloves are 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

EMDN code:

: T01020204 Nitrile examination treatment gloves

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,  
EN455-4:2009

EN 455 Standard Test Report

1. 7191280587-EEC22-01-WBH 2.7191280587-EEC22-02-WBH  
3. 7191280587-EEC22-03-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: Zibo, Shandong, China  
Date: 17 Aug 2022