
EU DECLARATION OF CONFORMITY

To the 2017/745 Medical Device Regulation 2016/425 Personal Protective Equipment regulation

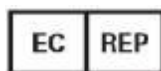
Doc No.: F-1129-D01

**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@lotusnl.com

Basic UDI-DI

69332655EM01021562864B

Product & Identification

942011 Peha-soft Nitrile Blue XS P150(BS01002016)

942012 Peha-soft Nitrile Blue S P150(BS01002017)

942013 Peha-soft Nitrile Blue M P150(BS01002018)

942014 Peha-soft Nitrile Blue L P150(BS01002019)

942015 Peha-soft Nitrile Blue XL P150 (BS01002020)

942025 Peha-soft Nitrile Blue XS P100(BS01002016)

942026 Peha-soft Nitrile Blue S P100(BS01002017)

942027 Peha-soft Nitrile Blue M P100(BS01002018)

942028 Peha-soft Nitrile Blue L P100(BS01002019)

942029 Peha-soft Nitrile Blue XL P100 (BS01002020)

**Intended purpose of the
product:**

Peha-soft Nitrile Blue Gloves, accelerator-free 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

EMDN code:

**T01020204 GUANTI NON CHIRURGICI IN NITRILE
EXAMINATION / TREATMENT GLOVES, NITRILE**

Manufacturer SRN Number:

CN-MF-000001139

European Authorized

Representative SRN Number:

NL-AP-000000121

Risk Classification:

Class 1

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.

We hereby declare that our EU Type Examination Certificate conformity the requirements of Annex V (Module B) of the regulation (EU) 2016/425 of the European Parliament and of the council. Follow the EU

Type-Examination the product has been shown to satisfy the applicable essential health and safety requirements of Annex of the PPE Regulation (EU) 2016/425 as a Category III product. The declaration of conformity is issued under the sole responsible of manufacturer.

The Personal Protective Equipment is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module D) under surveillance of the notify body SATRA Technology Europe Limited (2777).

Conformity Assessment Procedure

MDR Article 52(7)
PPE Article 19 (c,i)

Relevant Harmonized Standards:

EN 455-1: 2020/A1:2022,
EN 455-2:2015,
EN 455-3:2015,
EN 455-4:2009
EN ISO 21420:2020,
EN ISO 374-1:2016 + A1:2018,
EN ISO 374-5:2016

EN 455 Standard Test Report

1. 7191280587-EEC22-01-WBH
2. 7191280587-EEC22-02-WBH
3. 7191280587-EEC22-03-WBH
4. 7191294272-EEC22-01-WBH
5. 7191294272-EEC22-02-WBH

EN 374 Standard Test Report

1. CHT0312033/2116
2. CHM0313370/2120/JH
3. CHT0269325/1814/EN/C
4. CHT0275700/1838/LH
5. CHT0309411/2109
6. CHT0269325/1814

Notify Party:

SATRA Technology Europe Ltd.
Bracetown Business Park, Clonee, Dublin 15
Ireland (Notified Body 2777)

EU Type-Examination Certificate number:

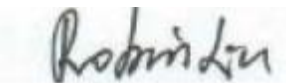
2777/24291-01/E00-00

Quality System Certificate

ISO 13485 Certificate No: Q5 062837 0012 Rev. 05
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:



Print Name: Robin Liu
Title: Quality Director
Place: Zibo, Shandong, China

Date: 29 Nov 2023