EU DECLARATION OF CONFORMITY

To the 2017/745 Medical Device Regulation

2016/425 Personal Protective Equipment regulation

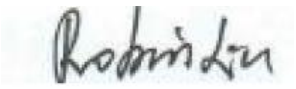
Doc No.: F-1129-D01

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(BS01002016) 942012 Peha-soft Nitrile Blue,S(BS01002017) 942013 Peha-soft Nitrile Blue,M(BS01002018) 942014 Peha-soft Nitrile Blue,L(BS01002019) 942015 Peha-soft Nitrile Blue,XL(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: **European Authorized Representative SRN Number:**	CN-MF-000001139 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 C2) 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, EN455-2:2015, EN455-3:2015, EN455-4:2009 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