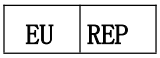
EU DECLARATION OF CONFORMITY

Doc No.:D-MDR-01/10-A05-PH

Identification of the Legal Manufacturer &Address	 :Blue Sail Medical Co.,Ltd :SRN Number:CN-MF-000001139 :No.21Qingtian Road,Qilu Chemical Industrial Park, Zibo,Shandong 255414 China
European Authorized Representative	 :Lotus NL B.V. :SRN Number:NL-AR-000000121 :Koningin Julianaplein 10,1e Verd,2595AA,The Hague,Netherlands :Email: info@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	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 and product	:56286 Nitrile examination/treatment glove,non-powdered,non-sterile
EMDN code	:T01020204 GUANTI NON CHIRURGICI IN NITRILE EXAMINATION/TREATMENT GLOVES,NITRILE
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.

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	:Article 52(7)and Annex VII,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	:ISO 13485:2016 :EN 455-1:2020/A2:2024,EN 455-2:2024,EN455-3:2023
EN455 Test Report	70.418.24.022.03A-00 70.418.24.022.03B-00 70.418.24.022.03C-00 70.418.24.022.03D-00 70.418.24.022.03E-00 70.418.24.022.11-00

EN374 Standard Test report CHT0312033/2116

CHM0313370/2120/JH

CHT0269325/1814/EN/C

CHT0309411/2109

CHT0269325/1814

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

EU Type-Examination Certificate No.: 2777/24291-01/E00-00

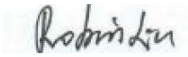
Quality System Certificate :Certificate No.Q50628370012 Rev.06

:Report No.BJ25092401

:Certificate Body:TÜV SÜD Product Service GmbH

:Issued Date:01 Aug 2025 Valid Date:31 Jul 2028

Identification of the person :Signed by:

Authorized to sign on behalf of the 

Legal Manufacturer

:Print Name:Robin Liu

:Title:Quality Director

:Location:Shandong,China

:Date:01 Aug 2025