

EU DECLARATION OF CONFORMITY

Doc No.:M-PPE02-B00

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

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| EC | REP |
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: Lotus NL B.V.
: Koningin Julianaplein 10, le Verd, 2595AA, The Hague,
Netherlands
: Email: peter@lotusnl.com

Product & Identification

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

Intended purpose of the product:

: The Peha-soft® Nitrile Blue 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

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 II of the PPE Regulation (EU) 2016/425 as a Category III product.

The declaration of conformity is issued under the sole responsible of manufacturer.

Relevant Harmonized Standards: : EN ISO 374-1:2016, EN ISO 374-5:2016, EN 420:2003 +A1:2009
Certification Body : SATRA Technology European Limited
Notified Body; : 2777
Expire Date: : 09 Nov 2023
Certificate number: : 2777/11521-02/E00-00

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 notified body SATRA Technology Europe Limited (2777).

Identification of the person

: Signed by

authorized to sign on behalf of

the Legal Manufacturer:

: Print Name: Robin Liu
: Title: Quality Director
: Place of Issue: Shandong, China
: Date: 22 Feb 2021