

2020年4月24日  
颁发日期

## EU DECLARATION OF CONFORMITY

Doc No.: D-MDR-01/08-A01

**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  
: Tel: +31 645171879 (English) +31626669008 (Dutch)  
: Email: [peter@loutsnl.com](mailto:peter@loutsnl.com)

**Basic UDI-DI**

: Details please reference the Article 1.1 part (4) of the CE technical files.

**Product & Identification**

: **Disposable Vinyl Patient Examination Gloves**

**Intended purpose of the product:**

The Disposable Vinyl Patient 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:**

: **47176 Vinyl examination/treatment glove, non-powdered**  
: **47177 Vinyl examination/treatment glove, powdered**  
: Detail product code, common specification please reference to Doc#:  
D-MDR-01/05-A00, Doc# D-MDR-01/02-A00 in the CE Technical Files.

**Risk Classification:**

: Class I, 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 4.1 Rule 1, Non-invasive device, and/or  
: Article 5.1 intended for transient use, Rule 5 of invasive device of Annex VIII.

**Conformity Route**

: Self-Declaration

**Relevant Harmonized Standards:**

: EN ISO13485:2016  
: EN 455-1: 2000, EN455-2:2015, EN455-3 2015, EN455-4:2009  
: EN ISO 374-1:2016, EN374-2: 2014, EN16523-1:2015, EN374-4:2013, ENISO 374-5:  
2016, EN420: 2003+A1:2009

**Certification Body**

: TUV SUD PSB Singapore

**Registration Date**

: 03 Feb 2020

**Registration No.**

: 04077/04078

**Quality System Certificate**

: Certificate No: Q5 062837 0012 Rev. 02  
: Certificate Body: TUV SUD Product Service GmbH  
: Issued Date: 12 Nov 2019

**Identification of the person  
authorized to sign on behalf of  
the Legal Manufacturer:**

: Signed by:

: Print Name: Robin Liu  
: Title: Quality Director  
: Place of Issue: Zibo, Shandong, China  
: Date: 24 Apr 2020

受控发行  
发行号: 2020年4月24日

# EU DECLARATION OF CONFORMITY

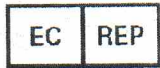
Doc No.: D-MDR-02/08-A01

Identification of the Legal  
Manufacturer & Address



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

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: Lotus NL B.V.  
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: Email: [peter@loutsnl.com](mailto:peter@loutsnl.com)

Basic UDI-DI

: Details please reference the Article 1.1 part (4) of the CE technical files.

Product & Identification

: **Disposable Nitrile Patient Examination Gloves**

Intended purpose of the product:

The Disposable Nitrile Patient 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**  
: Detail of product code, common specification please reference to Doc#:  
D-MDR-02/05-A01, Doc# D-MDR-02/02-A01 in the CE Technical Files.

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 4.1 Rule 1, Non-invasive device, and/or  
: Article 5.1 intended for transient use, Rule 5 of invasive device of Annex VIII.

Conformity Route

: Self-Declaration

Relevant Harmonized Standards:

: EN ISO13485:2016  
: EN 455-1: 2000, EN455-2:2015, EN455-3 2015, EN455-4:2009  
: EN ISO 374-1:2016, EN374-2: 2014, EN16523-1:2015, EN374-4:2013, ENISO 374-5:  
2016, EN420: 2003+A1:2009

Certification Body

: TUV SUD PSB Singapore

Registration Date

: 17 Apr 2020

Registration No.

: 04115

Quality System Certificate

: Certificate No: Q5 062837 0012 Rev. 02  
: Certificate Body: TUV SUD Product Service GmbH  
: Issued Date: 11 Nov 2019

Identification of the person  
authorized to sign on behalf of  
the Legal Manufacturer:

: Signed by:

: Print Name: Robin Liu  
: Title: Quality Director  
: Place of Issue: Zibo, Shandong, China  
: Date: 24 Apr 2020