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	EC REP :Lotus NL B.V. : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands :Tel: +31 645171879 （English） +31626669008 (Dutch) :Email: 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 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	: 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:	:Singed by: Robin Liu :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
European Authorized Representative	EC REP :Lotus NL B.V. : Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands :Tel: +31 645171879 （English） +31626669008 (Dutch) :Email: 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:	:Singed by: Robin Liu :Print Name: Robin Liu :Title: Quality Director :Place of Issue: Zibo, Shandong, China :Date: 24 Apr 2020