



IDENTIFICACIÓN DEL PRODUCTO	
Nombre:	Guante nitrilo de examinación azul celeste sin polvo.
Marca:	Heartmed
Material:	Nitrilo 100%, grado médico.
Color:	Azul celeste.
Tallas:	S / M / L / XL.
Presentación:	Caja x 100 unidades.

ESPECIFICACIONES TÉCNICAS			
Función:	Los guantes de nitrilo puro son una excelente barrera de protección biológica y química. Dan una mayor protección contra la abrasión y punción que el látex natural. Es un producto libre de látex, inodoro y ambidiestro. Las características del producto lo categorizan como un guante premium cuyo uso se extiende al área clínica/hospitalaria, farmacéutica, industrial y alimenticia.		
Látex:	No.	Estéril:	No.
Polvo:	No.		
Componente del polvo:	No aplica.		
Vigencia:	5 años a partir de la fecha de fabricación indicada en el empaque.		
Almacenamiento:	Lugar fresco y seco a temperatura entre 10° y 30° C.		
Uso:	Producto descartable para un solo uso. No reutilizar.		

CARACTERÍSTICAS DEL PRODUCTO					
Anatómico:	Si: <input checked="" type="checkbox"/>	No: <input type="checkbox"/>	Microtexturado:	Si: <input checked="" type="checkbox"/>	No: <input type="checkbox"/>
Suave:	Si: <input checked="" type="checkbox"/>	No: <input type="checkbox"/>	Hipoalergénico:	Si: <input checked="" type="checkbox"/>	No: <input type="checkbox"/>
- Guante anatómico, que disminuye la fatigabilidad en sus manos. - Textura suave para un calce cómodo. - Guantes microtexturado en dedos, palmas y puños. - Guante con una elasticidad, flexibilidad y mejor efecto memoria que los estándares conocidos. - Producto sintético que disminuye al mínimo alergias y/o problemas cutáneos. - Según "guante médico manual de orientación 2008 se recomienda que el guante sin polvo tenga menos de 2mg x guante". Tresor trabaja con menos de 1mg x guante de polvo, transformándose en un producto con una bioseguridad aumentada. Referencia Warning FDA, enero 2017.					

PROPIEDADES FÍSICAS					
Cont. Humedad:	Bajo 0,8% x unidad.			Elongación al quiebre (%):	Min. 750%
Largo (mm):	Min. 240 mm.			Resistencia a la tracción:	Min. 14 (MPa).
Grosor mínimo (mm):	Dedo	Palma	Puño	Proteína:	No aplica.
	0,09	0,06	0,05	Polvo:	Menos de 1 mg x dm².

CERTIFICACIONES



INFORMACIÓN CORPORATIVA	
TALLA	CÓDIGO INTERNO
S	GUANTENIAS75*
M	GUANTENIAM75*
L	GUANTENIAL75*
XL	GUANTENIAXL75*



Product Service

Certificate

No. Q5 062837 0012 Rev. 02

Holder of Certificate:

Blue Sail Medical Co., Ltd

No.21, Qingtian Road, Qilu Chemical Industrial Area
255414 Zibo, Shandong Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

**Design, Development, Production and Distribution
of Disposable Vinyl Examination Gloves,
Disposable Nitrile Examination Gloves.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ19924043

Valid from:

2019-11-12

Valid until:

2022-07-31

Date,

2019-11-12

Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 062837 0012 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Blue Sail Medical Co., Ltd
No.21, Qingtian Road, Qilu Chemical Industrial Area, 255414 Zibo,
Shandong Province, PEOPLE'S REPUBLIC OF CHINA

受控发行
发行号: 2020年4月24日

EU DECLARATION OF CONFORMITY

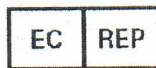
Doc No.: D-MDR-02/08-A01

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



: 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:

: Signed by:

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

Test Report No. 7191233436-EEC20/01-WBH
dated 13 Apr 2020



PSB Singapore

Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of Powder Free Nitrile Examination Gloves submitted by
Blue Sail Medical Co., Ltd. on 05 Mar 2020.

**Add value.
Inspire trust.**

TESTED FOR:

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

TEST DATE:

09 Mar 2020 to 09 Apr 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Brand/ Model	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Powder-Free Examination Gloves	BS 020- N01	Blue	01254511	XS	60	Blue Sail Medical Co., Ltd.
				01254512	S	60	
				01264711	M	60	
				01264712	L	60	
				01264921	XL	400	

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST:

1. EN 455-1:2000 Medical gloves for single use
Part 1: Requirements and testing for freedom from holes
2. EN 455-2:2015 Medical gloves for single use
Part 2: Requirements and testing for physical properties
3. EN 455-3:2015 Medical glove for single use
Part 3: Requirements and testing for biological evaluation



Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

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Fax : +65-6776 8670
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www.tuv-sud-psb.sg
Co. Reg : 199002667R

Regional Head Office:
TÜV SÜD Asia Pacific Pte. Ltd.
1 Science Park Drive, #02-01
Singapore 118221
TÜV®

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Table 1: Results for EN 455-1:2000

Clause	Tests	Size	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	XS	Shall not leak	10	315	0	Passed
		S		10	315	1	Passed
		M		10	315	1	Passed
		L		10	315	1	Passed
		XL		10	315	1	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Size	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	XS	≥ 240	13	243	Passed
		S		13	246	Passed
		M		13	242	Passed
		L		13	242	Passed
		XL		13	250	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	84	Passed
		M	95 ± 10	13	95	Passed
		L	110 ± 10	13	105	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	10.8	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.9	Passed
		XL		13	10.8	Passed
	b) Force at break after challenge testing (N) 7 days at $(70 \pm 2)^\circ\text{C}$	XS	For nitrile examination gloves: ≥ 6.0	13	9.6	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.3	Passed
		XL		13	10.8	Passed

Table 3: Results for EN 455-2:2015 Clause 7

Clause	Tests	Requirements	Results	Inferred results
7	Labelling	Manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.	Observed	Passed

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Table 4: Results for EN 455-3:2015 Clauses 4.2-4.5

Clause	Tests	Requirements	Results / Remarks	Inferred results
4.2	Chemicals	Gloves shall not be dressed with talcum powder (magnesium silicate).	Glove is powder-free glove, based on client's declaration letter version 2019001	NA
		Other chemicals	Manufacturer shall disclose upon request a list of chemical ingredients	NA
4.3 5.1	Endotoxins	< 20 EU/pair for gloves labelled with 'low endotoxin content'.	Not labelled with 'low endotoxin content'	NA
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	XS 0.04 mg per glove	Passed
			S 0.17 mg per glove	Passed
			M 0.51 mg per glove	Passed
			L 0.14 mg per glove	Passed
			XL 0.18 mg per glove	Passed
4.5 5.3	Proteins, leachable	The manufacturer shall strive to minimize the leachable protein level for gloves containing natural rubber latex.	Non-natural rubber latex glove	NA

Table 5: Results for EN 455-3:2015 Clause 4.6

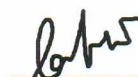
Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex;	NA
		The labelling shall include the following or equivalent warning statement together with the symbol: '(Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses';	NA
		b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;	Comply
		c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions';	NA
		d) for any medical glove containing natural rubber latex the product labelling shall not include: - any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein; - any unjustified indication of the presence of allergens;	NA
		e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.	NA
Inferred results			Passed

REMARKS:

1. Freedom from holes test for XS, S, M and L sizes were tested in manufacturer's site, witnessed by TÜV SÜD Certification and Testing (China) Co., Ltd. Beijing Branch on 04 Apr 2020.
2. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2019001.
3. NA: Not applicable for the submitted sample.



Yeo Poh Kwang
Associate Engineer



Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

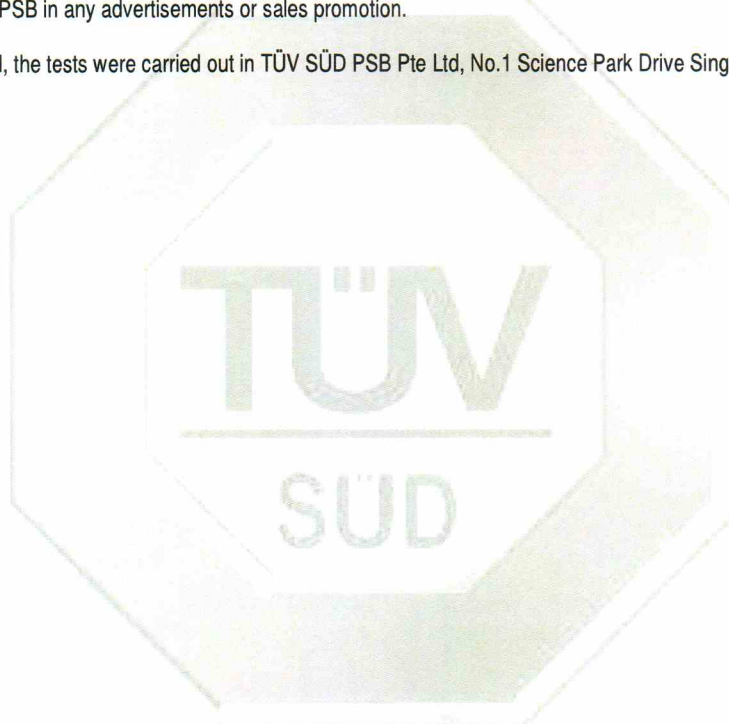


Photo : Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011





PSB Singapore

TEST CERTIFICATE

This Certificate is issued to

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

FOR

Product: Disposable Nitrile Powder-Free Examination Gloves

Brand/Model:

1. BS 020-N01
2. BS 020-N02
3. BS 020-N03
4. BS 020-N04
5. BS 020-N05

Product Details:

1. Sizes XS, S, M, L & XL, Powder-Free, Blue, Nitrile, Examination Glove
2. Sizes XS, S, M, L & XL, Powder-Free, White, Nitrile, Examination Glove
3. Sizes XS, S, M & L, Powder-Free, Blue Purple, Nitrile, Examination Glove
4. Sizes S, M, L & XL, Powder-Free, Black, Nitrile, Examination Glove
5. Sizes M & L, Powder-Free, Cobalt Blue, Nitrile, Examination Glove

Specification:

EN 455-1:2000
EN 455-2:2015
EN 455-3:2015

Test Report:

1. 7191233436-EEC20/01-WBH
2. 7191233436-EEC20/02-WBH
3. 7191233436-EEC20/03-WBH
4. 7191233436-EEC20/04-WBH
5. 7191233436-EEC20/05-WBH

Date of Test Report: 13 Apr 2020

Summary

A sample of product submitted was tested and found to comply with the requirements of the above standards.

TÜV SÜD PSB Pte Ltd

Certificate No:	Date of Original Issue:	Date of Last Revision:	Date of Expiry:
04115	17 Apr 2020	-	16 Apr 2022

This Certificate is part of a full report and should be read in conjunction with it. This Certificate remains the property of TÜV SÜD PSB Pte Ltd and shall be returned upon request. The use of this Certificate is subjected to the terms and conditions of the Test Certification Scheme.

Note: This Certificate is issued pursuant to the terms set out overleaf.