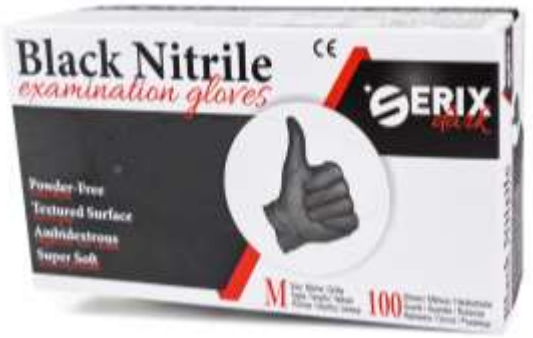
Technical Sheet

Product: Serix Dark Nitrile Powder-Free Examination Gloves
Manufacturer: Blue Sail Medical Co., Ltd
EC-REP: Lotus NL B.V.



Serix Dark Nitrile Powder-Free Examination Gloves

Description

The gloves are intended to be worn on the hands of healthcare personnel during medical examination procedure to protect cross contamination between healthcare personnel and patient.

Characteristics:

- Powder-Free Nitrile Examination Gloves
- This product is not made from natural rubber latex
- Textured finger. Non-sterile
- Design: ambidextrous with elastic cuff
- Protects against bacteria and fungi
- Color: black
- Packing: 100 pcs/box

Tested and certified for use in:

- Hospitals, Laboratories, Health Care Centers
- Dentistry
- Veterinary Clinics
- Food production and processing
- Cosmetics industry
- Hospitality industry: hotels, restaurants, catering

Instructions for use:

After use, wearers should visually check the gloves and remove any contamination from the outer surface before removing the gloves from the hands. Alternatively, carefully peel the gloves off the hands so that the contaminated outer gloves do not touch your skin.

Storage:

Store in original packaging in a dry and dark area, protected from ozone.

Technical data:

Size	Length (mm)	Width (mm)	Weight (g)	Thickness Cuff	Thickness Palm	Thickness Fingers	Force at break
XS	240	70 ± 10	2.8 ± 0.3	0.04 mm	0.06 mm	0.07 mm	6 N (Before Aging) 6 N (After Aging)
S		80 ± 10	3.0 ± 0.3				
M		95 ± 10	3.5 ± 0.3				
L		110 ± 10	4.0 ± 0.3				
XL		120 ± 10	4.5 ± 0.3				

Chemical Permeation:

Code letter	Chemical Permeation (EN ISO 374-1:2016)	Level	Mean Degradation (%) (En 374-4:2013)	
K	40% Sodium Hydroxide	6	-38.4	Degradation levels indicate the change in Puncture Resistance of the glove after exposure to the tested chemical.
P	30% Hydrogen Peroxide	2	17.6	
J	n-heptane	0	27.4	
O	25% Ammonium hydroxide	0	29.9	
T	37% Formaldehyde	5	46.6	

Certifications and standards:

- EN 455-1:2000, EN455-2:2015, EN 455-3:2015, EN455-4:2009
- EN 420:2003 + A1:2009 (Palm Protection)
- EN ISO 374-1:2016/Type B, EN ISO 374-5:2016
- ISO 13485
- 2777 Comply to PPE Regulation 2016/425 Cat IIII

Serix Dark Nitrile Powder-Free Examination Gloves

EU DECLARATION OF CONFORMITY

Doc No.: D-MDR-02/08-A04

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 Email: [illegible]
Basic UDI-DI	69332655MD0102156286TC
Product & Identification	**Disposable Nitrile Examination Gloves, Powder Free**
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:	**T010202024 GUANTI NON CHIRURGICI IN NITRILE** EXAMINATION / TREATMENT GLOVES, NITRILE
Manufacturer SRN Number:	CN-MF-000001139
REP SRN Number:	NL-AP-000000121
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 52(7) and Annex VIII, 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:	EN ISO13485:2016 EN 455-1: 2000, EN455-2:2015, EN455-3:2015, EN455-4:2009
EN 455 Standard 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
Quality System Certificate	ISO 13485 Certificate No. Q5 062837 0012 Rev. 02 Certificate Body: TUV SUD Product Service GmbH Issued Date: 12 Nov 2019 Valid Date: 31 Jul 2022
Identification of the person authorized to sign on behalf of the Legal Manufacturer:	Signed by: Print Name: Robin Liu Title: Quality Director Place: Zibo, Shandong, China Date: 28 May 2021

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TEST CERTIFICATE

TÜV PSB Singapore

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

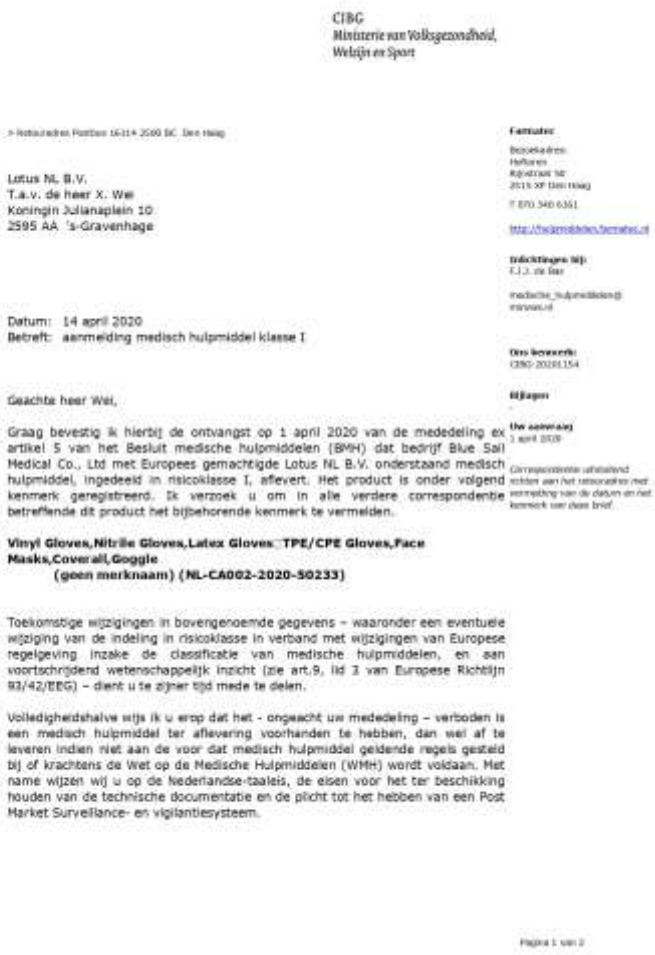
This Certificate is part of a full report and should be read in conjunction with it. This Certificate remains the property of TÜV SÜD PSB Pte Ltd and shall be returned upon request. The use of this Certificate is subjected to the terms and conditions of the Test Certification Scheme.

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

TÜV SÜD PSB Pte Ltd - 1 Science Park Drive - Singapore 118221

TÜV®

Serix Dark Nitrile Powder-Free Examination Gloves



CIBG
Ministerie van Volksgezondheid,
Welzijn en Sport

Lotus NL B.V.
T.a.v. de heer X. Wei
Koningin Julianaplein 10
2595 AA 's-Gravenhage

Datum: 14 april 2020
Betreft: aanmelding medisch hulpmiddel klasse I

Geachte heer Wei,

Graag bevestig ik hierbij de ontvangst op 1 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf Blue Sail Medical Co., Ltd met Europees gemachtigde Lotus NL B.V. onderstaand medisch hulpmiddel, ingedeeld in risicoklasse I, aflevert. Het product is onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende dit product het bijbehorende kenmerk te vermelden.

Vinyl Gloves,Nitrile Gloves,Latex Gloves,TPE/CPE Gloves,Face Masks,Coverall,Goggle
(geen merknaam) (NL-CA002-2020-50233)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Farmatec
Bezoekadres:
Hefbaan
Rijnstraat 50
2515 XP Den Haag
T 070 340 6361
http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
E.J.J. de Bas
medische_hulpmiddelen@
minvws.nl

Ons kenmerk:
CIBG-20201154

Bijlagen
-

Uw aanvraag
1 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Pagina 1 van 2

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van het bovengenoemde product slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van het desbetreffende product als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dhr. M.J. van de Velde

Pagina 2 van 2

Serix Dark Nitrile Powder-Free Examination Gloves

ARDL
Progress Through Innovation, Technology and Customer Satisfaction

April 29, 2017

• TEST REPORT •

PN 133966

CHEMICAL ANALYTICAL SERVICES

Robin Liu
Blue Sail Medical
No. 48 Yinuo Road,
Jixia Street,Linzi District,
Zibo Shangdong,
255400
China

Prepared By: Tiffany L. Heller
Assistant Manager, Pharmaceutical Services

Approved By: Ana C. Barbur, M.S.
Manager, Chemical, Microbiological, & Pharmaceutical Services

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ISO 9001:2008

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Progress Through Innovation, Technology and Customer Satisfaction

April 29, 2017

Robin Liu
Blue Sail Medical

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: Glove sample identified as Nitrile Patient Examination Gloves, Powder Free, Blue, and Tested for Use with Chemotherapy Drugs; Lot# BSS042-111.

TESTING CHEMOTHERAPY DRUGS:
Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	USP; Lot# R071D0; Expiration 03/2018
Cisplatin, 1.0 mg/ml (1,000 ppm)	Fresenius Kabi; Lot# 6114286; 01/2018
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Sigma Aldrich; Lot# BCBM8984V; Expiration 04/2017
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31321665B; Expiration 09/2019
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# PT04300; Expiration 10/2018
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Sigma Aldrich; Lot# 0711BJJV; Expiration 01/2018
Methotrexate, 25 mg/ml, (25,000 ppm)	Teva; Lot# 16A28MA, Expiration 01/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma Aldrich; Lot# SLBH6728V; Expiration 05/2018
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	Hospira; Lot# C128865AA; Expiration 12/2017
Thiotepa, 10.0 mg/ml (10,000 ppm)	USP; Lot# R046R0; Expiration 01/2018
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# SLBQ8329V; Expiration 01/2018

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

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Fax (330) 794-6610 | Worldwide (330) 794-6600

Serix Dark Nitrile Powder-Free Examination Gloves

COLLECTION MEDIA:
The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	Distilled Water
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

DETECTION METHOD OF CHEMICAL PERMEATION: UV/VIS ABSORPTION SPECTROMETRY:

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Methotrexate, 25 mg/ml (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	194
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens: Nitrile Patient Examination Gloves, Powder Free, Blue and Tested for Use with Chemotherapy Drugs; Lot# BS9042-111.

Testing Chemotherapy Drugs	Thickness (mm)				Weight/Unit Area (g/m²)
	Sample 1	Sample 2	Sample 3	Average (mm)	
Carmustine (BCNU)	0.063	0.060	0.064	0.062	65.6
Cisplatin	0.065	0.065	0.061	0.064	
Cyclophosphamide (Cytoxan)	0.061	0.060	0.064	0.062	
Doxorubicin Hydrochloride	0.065	0.063	0.062	0.063	
Etoposide (Toposar)	0.059	0.065	0.061	0.062	
Fluorouracil	0.059	0.066	0.064	0.063	
Methotrexate	0.059	0.063	0.064	0.062	
Mitomycin C	0.063	0.062	0.065	0.063	
Mechlorethamine	0.061	0.066	0.063	0.063	
Paclitaxel (Taxol)	0.062	0.064	0.060	0.062	
Thiotepa	0.059	0.064	0.061	0.061	
Vincristine Sulfate	0.066	0.061	0.059	0.062	

RESULTS:

Table 5. Permeation Test Results on: Nitrile Patient Examination Gloves, Powder Free, Blue, and Tested for Use with Chemotherapy Drugs; Lot# BS9042-111.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	35.3 (58.5,35.3,57.5)	0.3 (0.2,0.4,0.2)	Moderate swelling and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mechlorethamine HCl, 1.0 mg/ml (1,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	29.2 (37.7,37.5,29.2)	0.2 (0.3,0.1,0.3)	Slight swelling and no degradation
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany C. Heller
Assistant Manager
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S.
Manager
Chemical, Microbiological and Pharmaceutical Services

Serix Dark Nitrile Powder-Free Examination Gloves

ARDL

Testing. Development. Problem Solving.

April 19, 2018

• TEST REPORT •

PN 141013

CHEMICAL ANALYTICAL SERVICES

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Assistant Manager, Pharmaceutical Services

Approved By: Ana C. Barbur, M.S.
Vice President, Analytical & Chemical Services

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ISO 9001:2008

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Testing. Development. Problem Solving.

April 19, 2018

Blue Sail Medical
Robin Liu

SUBJECT: Permeation testing per ASTM D 6978 on sample submitted by the above company.

RECEIVED: One glove type identified as Nitrile Patient Examination Gloves, Powder Free, Blue, Tested for use with Chemotherapy Drugs. Lot# BS9042-111.

TEST DRUG:
Table 1: List of the Testing Drugs, Sources, and Expiration Dates

TESTING DRUG	DRUG SOURCE
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Teva, Lot# 31322092B, Expiration 11/2019

COLLECTION MEDIA:
The collection media, which were selected, are listed in Table 2.

Table 2: Collection Media for Testing Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area
Deviation from Standard Test Method:	Used 1" Permeation Cell

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Fax (330) 794-6610 | Worldwide (330) 794-6600

Blue Sail Medical
Robin Liu

DETECTION METHOD OF CHEMICAL PERMEATION: UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25
UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 milliliter/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3: Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TEST DRUG	WAVELENGTH (nm)
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320

SAMPLE CHARACTERISTICS:

Table 4: Thickness characteristics for the tested specimens: Nitrile Patient Examination Gloves, Powder Free, Blue, Tested for use with Chemotherapy Drugs, Lot# BS9042-111.

Testing Drug	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Dacarbazine	0.068	0.070	0.070	0.069	67.0

RESULTS:

Table 5: Permeation Test Results on Nitrile Patient Examination Gloves, Powder Free, Blue, Tested for use with Chemotherapy Drugs, Lot# BS9042-111.

TEST DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No Breakthrough up to 240 minutes	N/A	Slight swelling, no degradation

Tiffany L. Heller
Assistant Manager,
Pharmaceutical Services
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S.
Vice President,
Analytical & Chemical Services

Serix Dark Nitrile Powder-Free Examination Gloves

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

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.

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:
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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	10.6	Passed
		S		13	8.7	Passed
		M		13	8.0	Passed
		L		13	10.9	Passed
		XL		13	10.6	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°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

Serix Dark Nitrile Powder-Free Examination Gloves

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

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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:

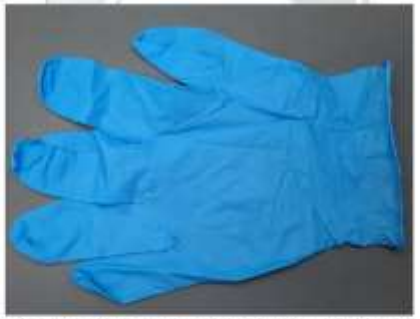

Photo : Disposable Nitrile Powder-Free Examination Gloves, BS 020-N01, Blue

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