



CAUTION

These gloves are sometimes subject to failure and may puncture or tear if donned improperly. Discontinue use if damaged. Store in a cool place, avoid excessive heat 40°C (104°F). Do not store in highly humid or damp areas. Shield open box from direct sun, fluorescent lighting, or excess ozone conditions. Primary material Synthetic Nitrile Rubber (Nitrile). Does not contain natural rubber latex. Components used in making gloves may cause allergic reactions in some users. The buyer & user have examined these gloves after having read the cautionary statements, and have determined them to be fit for the purpose of general purpose and cleaning in non-sterile environments. The manufacturer, its resellers, agents & their employees are not responsible for any other claims or representations. No warranty implied.

LEVEL	AQL	TEST LEVELS
Level 3	< 0.65	G1
Level 2	< 1.5	G1
Level 1	< 4.0	S4

EN ISO 374-1:2016	EN 16523-1:2015	EN 374-4:2013
Chemical	Level 0	< 38.40%
40% Sodium Hydroxide (K)	Level 2	17.60%
30% Hydrogen Peroxide (P)	Level 5	46.60%
37% Formaldehyde (T)		

Level 1 > 10mins, Level 2 > 30mins, Level 3 > 60mins
Level 4 > 120mins, Level 5 > 240mins, Level 6 > 480mins

EC type examination and Module C2 carried out by SATRA Technology Europe Ltd, Bracetown Business Park, Clonsilla, Dublin 15, Dublin, Ireland. Nitrified body 2777



Meets the requirements of:
EN ISO 374-1:2016 EN 455-1:2000
EN 374-2:2004 EN 455-2:2005
EN 16523-1:2015 EN 455-3:2015
EN 374-4:2013 EN 455-4:2009
EN ISO 374-5:2016 EN 1188-1:2007
EN 455-2003+A1:2009 EN 13130-1:2004
ASTM F 1671-2013

GB: Examination gloves. Nitrile. Powder-Free, non-sterile, ambidextrous. Storage: -10-40°C protect from heat, moist, light and ozone. **BAR:** Rukavice za pregled, nitrilne, bez pudera, nesterilne, obebojne. Skladovanje: -10-40°C, zaštititi od toplote, vlage, svetlosti i ozona. **BG:** Pregledna rękawica, nitrilowa, bez pudru, nesterilna, niebarwiona. Składowanie: -10-40°C, chronić przed ciepłem, wilgocią, światłem i ozonem. **CZ:** Vykvalifikační rukavice, nitril, nepudrová, nesterilní, obojručí. Skladování: -10-40°C, chránit před teplem, vlhkostí, světlem a ozonem. **DE:** Untersuchungshandschuhe, Nitril, puderfrei, unsteril, beidhändig. Aufbewahrung: -10-40°C, vor Wärme, Feuchtigkeit, Licht und Ozon schützen. **DK:** Undersøgelseshandsker, nitril, pudrefri, unsteril, passer til både højre og venstre hånd. Opbevaring: -10-40°C, beskyttes mod varme, fugt, stærkt lys og ozon. **EE:** Lõhvatõkestavad nitril, pudrita, nesterilised, mõlemale käele. Hoidmistemperatuur: -10-40°C, hoida kuumuse, niiskuse, valguse ja ozooni eest kaetud. **ES:** Guantes de examen, nitrilo, sin polvo, sin esterilizar, ambidiestro. Guardado: -10-40°C protegidos del calor, la humedad, la luz y el ozono. **FI:** Tutkimuskäsineet, nitril, pudertonta ei-steriili, molempikäinen. Säilytys: -10-40°C suojaa kuumuudelta, kostealta, valolta ja ozonilta. **FR:** Gants d'examen en nitrile, non pudrés, non-steriles, ambidextres. Stockage: -10-40°C à protéger de la chaleur, de l'humidité, de la lumière intense et de l'ozone. **GR:** Εξaminεσες γυμνασες γυμνασες, χωρίς pudra, unsteril, amfidekstra. Αποθηκεύονται: -10-40°C προστασία από θερμότητα, υγρασία, έντονο φως και οξυγόνο. **HR:** Rukavice za pregled, nitrilne, bez pudera, nesterilne, obebojne. Skladovanje: -10-40°C, zaštititi od toplote, vlage, svetlosti i ozona. **HU:** Vizsgálókesztyű, nitril, pudertelen, nem steril, kétkezes. Tárolás: -10-40°C, hő, nedvesség, fény és ozon elől védeni. **IS:** Skoðunarrúkkar, nitril, pudrafur, ósteril, passa bæði smátt og hágrátt hönd. Geymsla: -10-40°C, forðist hita, raka og sekti frá eða sátt. **IT:** Guanti da esame in nitrile, non pudrati, non-sterili, ambidestri. Conservazione: -10-40°C al riparo da fonti di calore, umidità, luce e ozono. **LT:** Apžiūros pirštinės, nitrilinės, be miltelių, nesterilios, tinka abiejų rankoms. Laikymo sąlygos: -10-40°C. Saugokit nuo šilumos, drėgmės, šviesos ir ozono. **LX:** Pregledna omča, nitril, nepudrta, nesteril, obojručna. Skladišanje: -10-40°C zaštititi pred toploto, vlago, svetlobo in ozon. **NL:** Onderzoekshandschoenen, nitril, powderloos, niet-steriel voor zowel links- als rechtshandig gebruik. Bewaren: -10-40°C beschermen tegen hitte, vocht, licht en ozon. **PL:** Rękawica badawcza, nitrilowa, nieposrecona, niesrecona, obojuczna. Przechowywanie: -10-40°C, chronić przed ciepłem, wilgocią, światłem i ozonem. **PT:** Luvas de exame, de nitrilo, sem pó, não esterilizadas, ambidiestras. Depozitar: -10-40°C proteger impetiva calor, umidade, luz e ozono. **RO:** Mănuși pentru examinare, Nitril, fără pudră, nesteril, ambidestru. Depozitare: -10-40°C protejati împotriva căldurii, umidității, luminii și ozonului. **RU:** Перчатки контрольные, нитриловые, нестерилизованные, неопудренные, амбидекстрные. Амбарное хранение: -10-40°C защитить от жары, влажности, света и озона. **SE:** Undersökningshandske, nitril, pudrefri, obojrukt, passar bäde vänster och höger hand. Förvaring: -10-40°C skyddas från värme, fukt, ljus och ozon. **SI:** Zaščitne rokavice iz nitrila, brez pudre, nesterilne, obebojne. Shranjevanje: -10-40°C, ne izpostavljajte vročini, vlazi, svetlobi in ozonu. **SK:** Vykvalifikačné rukavice, nitrilové, nepudrované, nesterilné, obojručné. Skladovanie pri -10-40°C, chránite pred svetlom, teplotou, vlhkosťou a ozónom. **TR:** Nitril, pudrasız, non-steril, ambidestri. Muayene eldiverleri. Saklama koşulları: Soğukluk nem ve nemden koruyun ve -10-40°C arasında saklayın. **UA:** Руківки для огляду, нитрилові, неопудровані, нестерильні, амбидекстрні. Зберіть у сухому місці при температурі -10-40°C, уникати впливу високої температури, прямого сонячного проміння, вологості. **IL:** כפפות בדיקה נייטריליות ללא אבק, לא סטריליות, אמבדקטריות. אחסון: -10-40°C, מניחים מול חום, לחות, אור ורייח. **SA:** قفازات لفحص، نيتريلا، غير معقمة، غير مغطاة. **IN:** कनिट्रिल, नैपुड्रेड, नैस्टेरिल, अंबिडैक्सट्र. **PK:** نٹریل، پوڈر فری، غیر سٹیریل، امبائیڈیکٹر. **RU:** Перчатки для осмотра, нитриловые, неопудренные, нестерильные, амбидекстрные. **UA:** Руківки для огляду, нитрилові, неопудровані, нестерильні, амбидекстрні. Зберіть у сухому місці при температурі -10-40°C, уникати впливу високої температури, прямого сонячного проміння, вологості.

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Importer
Arco Limited
PO BOX 21 HULL,
HU1 2SU UK

LOT 4512161998 | 2021-01 | 2026-01



Disposable Nitrile Examination Gloves

S POWDER FREE-BLUE | 100 Pcs



Protecting Your World

Powder Free | Latex Free | Non-sterile | Ambidextrous | Single Use Only | Chlorinated | Finger Textured



Certificate

No. Q5 062837 0012 Rev. 02

Holder of Certificate: Blue Sail Medical Co., Ltd

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

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



PSB Singapore

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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



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Co. Reg : 199002667R

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

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±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

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

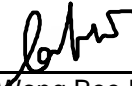
Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the 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.
4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011



Test Report No. 7191233436-EEC20/03-WBH
dated 13 Apr 2020



PSB Singapore

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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-N03	Blue Purple	02153711	XS	60	Blue Sail Medical Co., Ltd.
				02163811	S	60	
				02153922	M	60	
				02164612	L	60	

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



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Co. Reg : 199002667R

Regional Head Office:
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1 Science Park Drive, #02-01
Singapore 118221
TUV

RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N03, Blue Purple

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	0	Passed
		L		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	240	Passed
		S		13	242	Passed
		M		13	248	Passed
		L		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	80	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	104	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.2	Passed
		S		13	6.6	Passed
		M		13	6.4	Passed
		L		13	6.3	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	XS	For nitrile examination gloves: ≥ 6.0	13	6.8	Passed
		S		13	6.9	Passed
		M		13	6.3	Passed
		L		13	6.9	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-N03, Blue Purple

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	0.02 mg per glove	Passed
			S	0.06 mg per glove	Passed
			M	0.27 mg per glove	Passed
			L	0.24 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

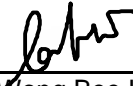
Clause	Tests	Requirements	Results
4.6	Labelling	In addition to the labelling specified in EN 1041:2008+A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:	
		a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the 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-N03, Blue Purple

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