





Batch number: 11420309
Good for use until: 04-2023

גודל: L



קידום מכירות ארוך ומסווג כג'ויס
שיווקי או ג'ויס
Made in VietNam

הגדרת המוצר
כפפות ניטריל שחורות ללא אבקה רפואיות, מתאימות לשימוש רפואי ועוד. עמידות כימיקלים, להגנה על העובד/ת מפגיעות מכניות וכימיות, אינן מכילות חלבונים מן הצומח. כפפות ניטריל מתאימות לשימושים בתעשיות המזון, ניקיון, תעשייה, פארמה ועוד.
בעלות עמידות גבוהה לסולבנטים מבוססי נפט, בסיסים, כהלים, שמנים ומינרלים. עמידות פחותה לקטונים ופחמנים ארומטיים.

אופן השימוש
כפפה לשימוש חד פעמי
יש להשליך בגמר השימוש למיחזור
ניתן להשתמש בשני כפפות אחת על השנייה במגע עם חומרים מסוכנים

אחסון
יש לאחסן במקום מוצל ויבש, אין לחשוף ישירות לשמש או לאור פלורסנט ישיר

אזהרה
עלול לגרום לתופעות אלרגיות במקרים מסוימים. במקרה כזה יש להפסיק להשתמש במוצר זה.

כמות: כ-100 יחידות
±5% בקרטון

Certificación de calidad

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



PSB Singapore

TEST CERTIFICATE

This Certificate is issued to

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.

TUV SUD 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

TUV®

Certificación de calidad

此文件仅限 ZG-JC-GM-008
使用, 再次复制或转发无效

Test Report No. 7191233436-EEC20/04-WBH
dated 13 Apr 2020



PSB Singapore

Add value.
Inspire trust.

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
on 05 Mar 2020.

TESTED FOR:

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-N04	Black	02066011	S	60	Blue Sail Medical Co., Ltd.
				02066122	M	60	
				02094911	L	60	
				02092311	XL	400	

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

METHOD OF TEST:

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



Laboratory:
TUV SUD PSB Pte. Ltd.
No 1 Science Park Drive
Singapore 118221

Phone: +65-6885 1333
Fax: +65-6776 8670
E-mail: enquires@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg: 199002667R

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

Certificación de calidad

此文件仅限 ZG-JC-GM-008
使用，再次复制或转发无效

Report No. 7191233436-EEC20/04-WBH
dated 13 Apr 2020



RESULTS:

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N04, Black

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	S	Shall not leak	10	315	0	Passed
		M		10	315	1	Passed
		L		10	315	0	Passed
		XL		10	315	3	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)	S	≥ 240	13	240	Passed
		M		13	246	Passed
		L		13	243	Passed
		XL		13	245	Passed
	b) Width (mm)	S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	104	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	S	For nitrile examination gloves: ≥ 6.0	13	7.6	Passed
		M		13	10.0	Passed
		L		13	10.2	Passed
		XL		13	11.2	Passed
	b) Force at break after challenge testing (N) 7 days at (70±2)°C	S	For nitrile examination gloves: ≥ 6.0	13	7.5	Passed
		M		13	9.5	Passed
		L		13	9.0	Passed
		XL		13	10.9	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

Certificación de calidad

此文件仅限 ZG-JC-GM-008
使用, 再次复制或转发无效

Report No. 7191233436-EEC20/04-WBH
dated 13 Apr 2020



PSB Singapore

RESULTS (cont'd):

Sample: Disposable Nitrile Powder-Free Examination Gloves, BS 020-N04, Black

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.	S 0.07 mg per glove	Passed
			M 0.09 mg per glove	Passed
			L 0.16 mg per glove	Passed
			XL 0.12 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:	NA
		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; 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

Certificación de calidad


此文件仅限 ZG-JC-GM-008
使用, 再次复制或转发无效


Report No. 7191233436-EEC20/04-WBH
dated 13 Apr 2020



REMARKS:

1. Freedom from holes test for 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-N04, Black

Certificación de calidad

此文件仅限 ZG-JC-GM-008
使用，再次复制或转发无效

st Report No. 7191233436-EEC20/04-WBH
dated 13 Apr 2020

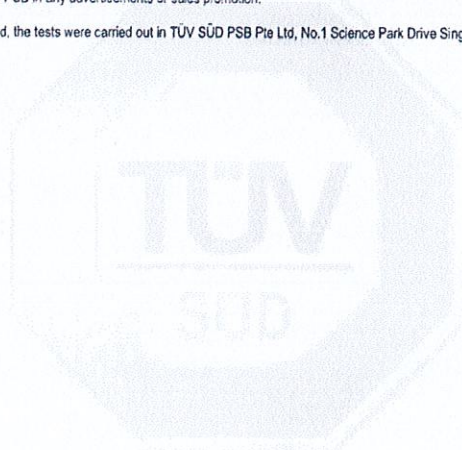


PSB Singapore

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



Guantes de nitrilo sin polvo no esterilizados

Características del producto

Referencia:	2777/11024-02/E00-00
Modelo:	Non-Sterile Powder Free Nitrile Disposable Glove
Color:	Negro
Tamaños:	11.600 Small 4.600 Medium 11.600 Large
Presentación:	Cajas de 100 unidades
Certificaciones válidas	ver adjunto
Cantidad:	27.800 cajas

