FIRST TOUCH

In an average manufacturing process, gloves and masks may come in human skin contact up to 8 times. With ultimate hygiene in mind, Cranberry products are First Touch® manufactured, examined, and packaged with zero direct skin contact exposure. Don't just put on any gloves and masks, look for our First Touch® logo and be assured that you are doing the best you can to protect yourself and your patients.

CERTIFICATIONS

Quality Managment Systems

ISO 13485 & ISO 9001

TGA AUSTRALIA

SMG POWDERED

CE

FDA

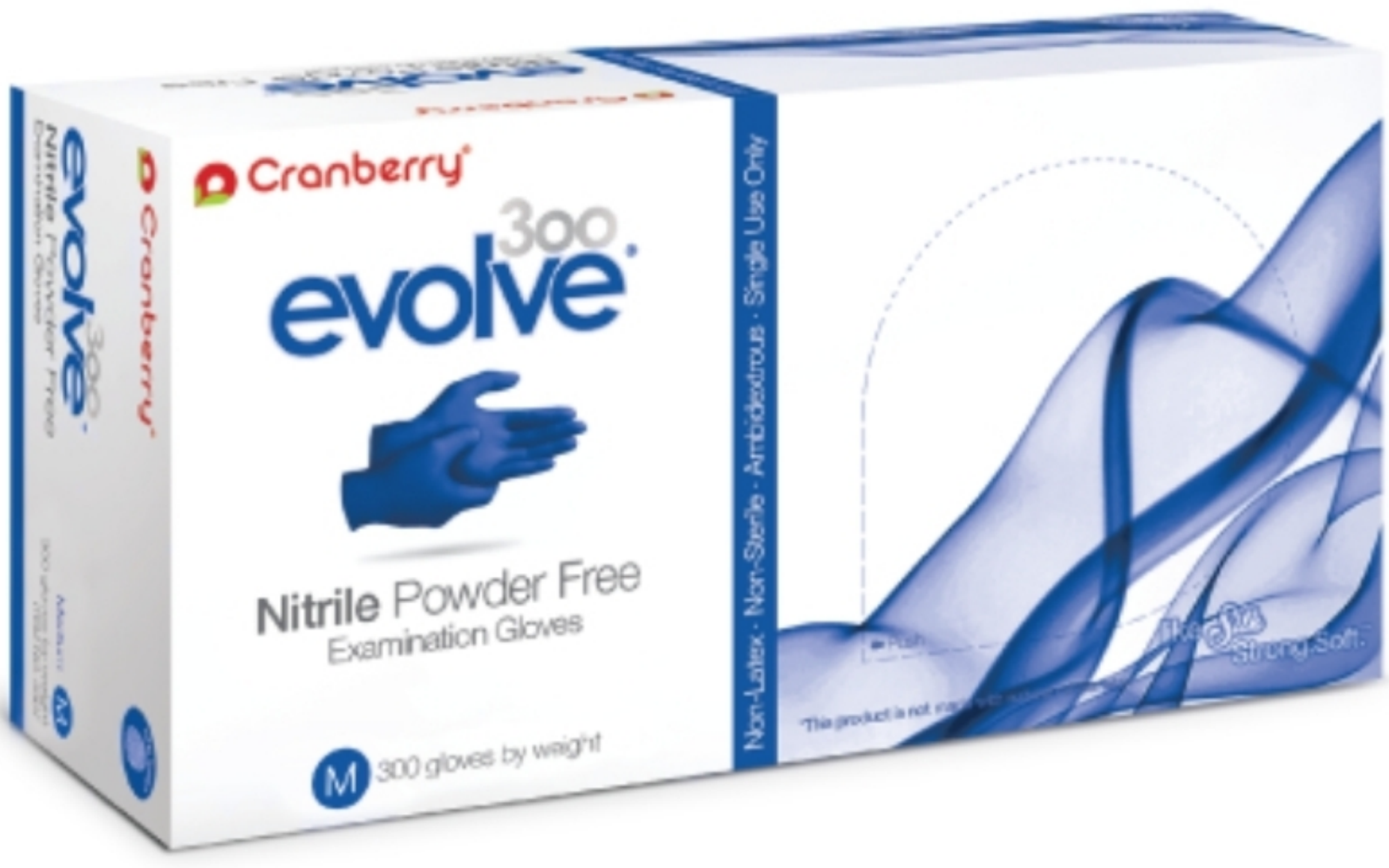
MDL Health Canada

CGSB ONGC

evolve 300®

Nitrile Powder Free Examination Gloves

The Evolve 300 Nitrile Powder Free Examination Gloves are Cranberry's latest and softest gloves yet, combining comfort and tensile strength without sacrificing tactile sensitivity. Cranberry's exclusive EvoSoft™ formulation gives Evolve a unique silk-like attribute that is both soft and strong with textured fingertips for precise gripping under all operating conditions.



Awards


Dental
PRODUCT
SHOPPER
BEST PRODUCT
2014

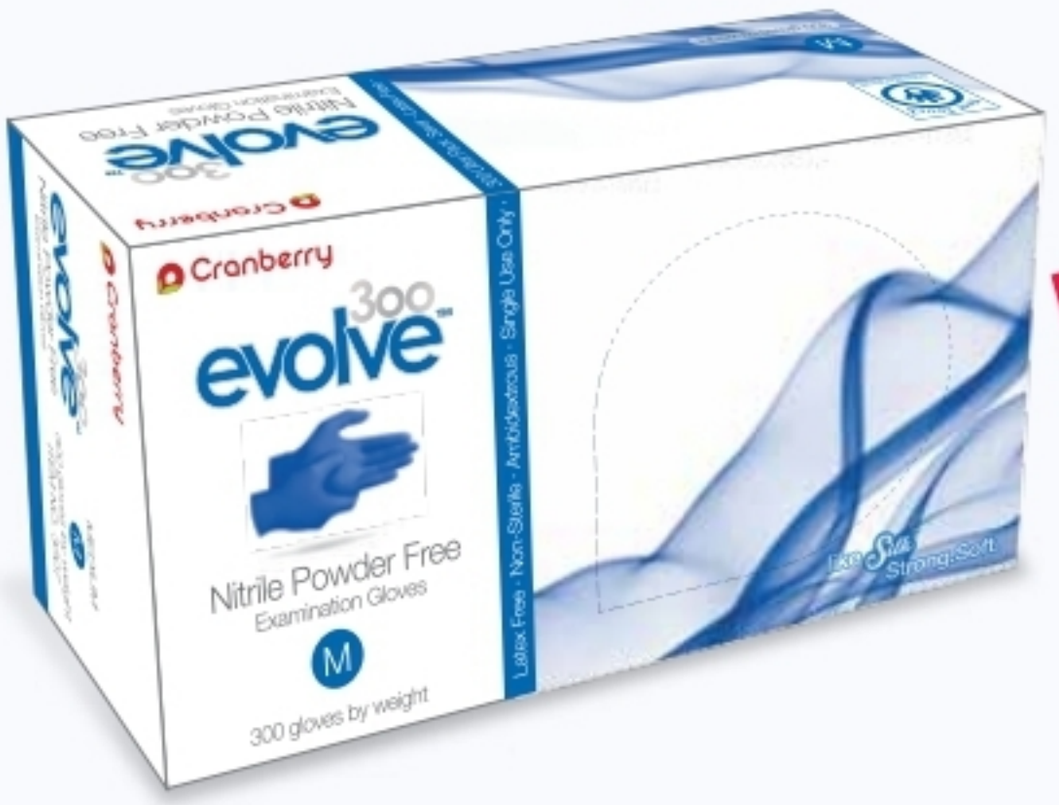

Dental
PRODUCT
SHOPPER
BEST PRODUCT
2015


EDITORS'
THE DENTAL ADVISOR
++++½
CHOICE

Cranberry®

like Silk™

Strong.Soft.



NEW

evolve 300™ Nitrile
Powder Free Exam Gloves

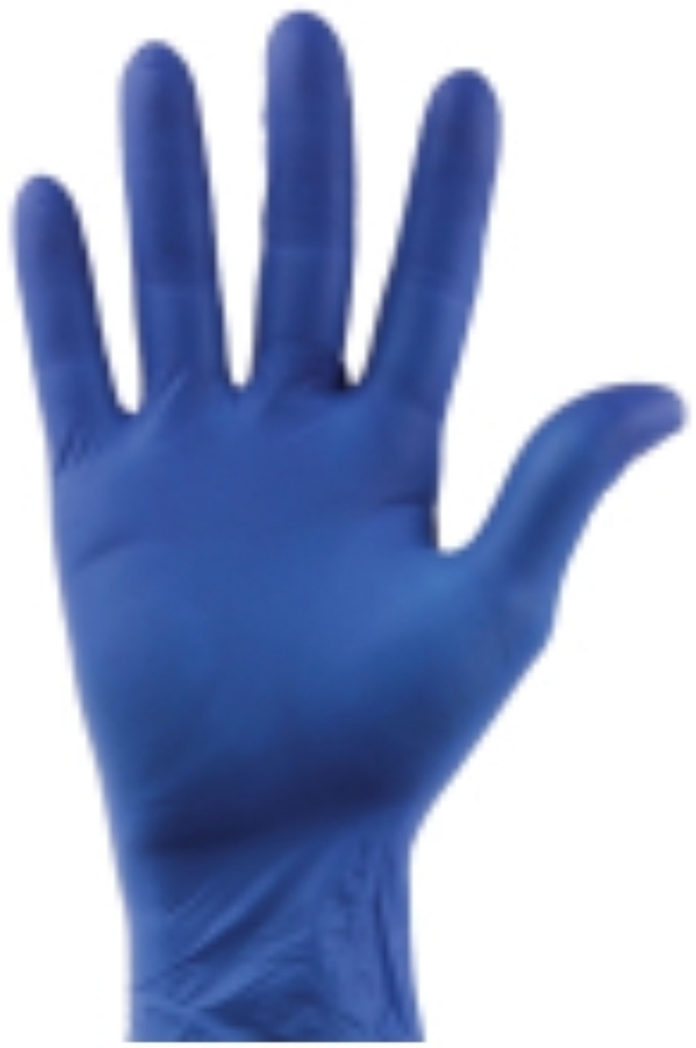
- Exclusive EvoSoft™ formulation delivers silk-like attribute, soft yet strong
- Superior tensile strength for maximum stretch
- Strong Cuff for Tear Resistance
- Ultra Space Saver Pack **(300 gloves per box)**

XS	[3305]
S	[3306]
M	[3307]
L	[3308]
XL*	[3309]

300 gloves/box, 10 boxes/case; *XL: 250 gloves/box

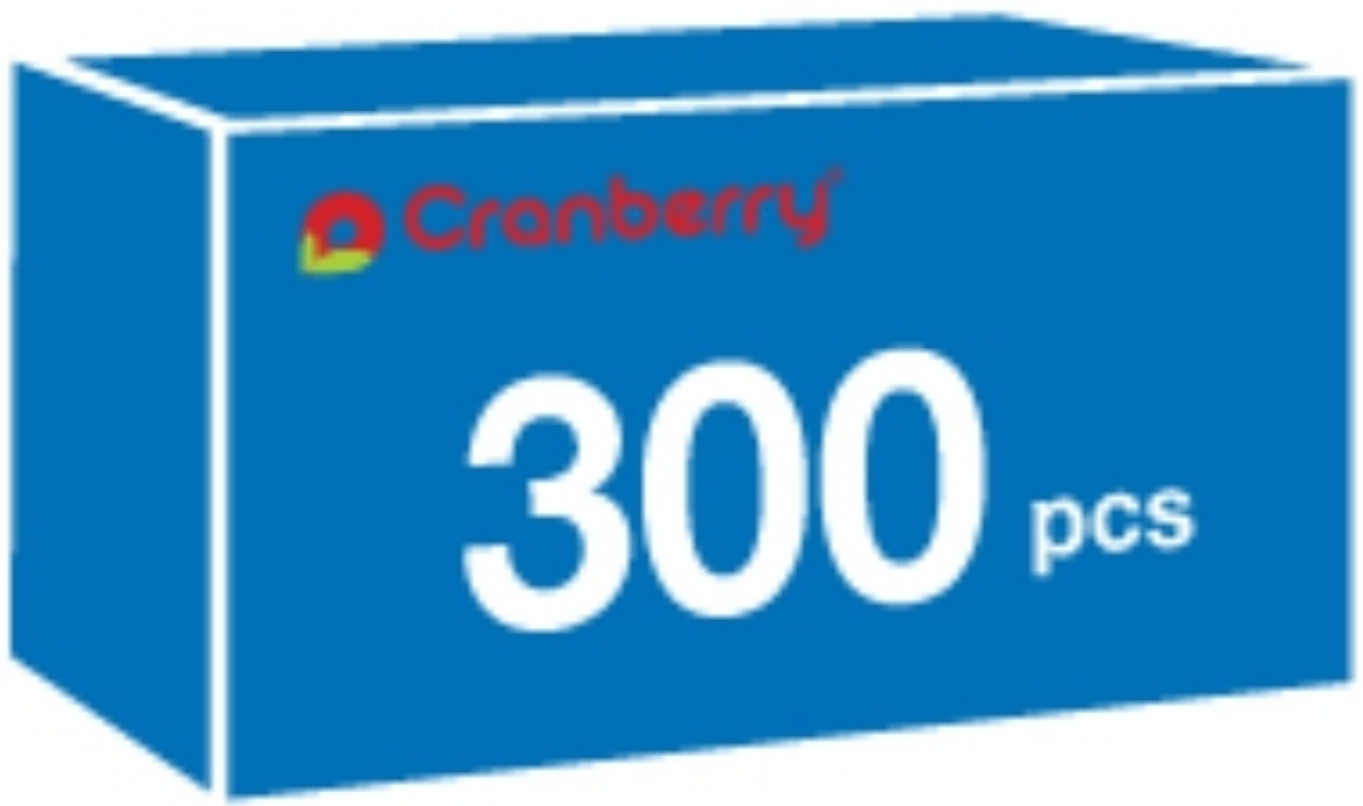
FORMFITTING

EvoSoft™ formulation delivers a silk-like attribute, soft and strong. Fingertip textured in a Royal Blue color.



SILK THIN

Our stretchiest gloves yet, high tensile strength and excellent comfort, while not sacrificing tactile sensitivity.



300 GLOVES PER BOX

Ultra 300 Saver Pack reduces storage space and packaging waste.

evolve 300™ Nitrile Powder Free Exam Gloves

Features	Benefits
Exclusive EvoSoft™ formulation	Provides unprecedented soft and strong comfort during extended wear
Textured Fingertips	Delivers good grip
300 Space Saver Pack	Maximize storage space and efficiency

Recommended for use when:
i) A latex-free, powder-free solution is required.
ii) Seeking a soft and tear-resistant, protective solution with good grip.
iii) Seeking space-saving, reduced waste packaging.

Physical Data

Dimension	Extra-Small	Small	Medium	Large	Extra-Large
Length (mm) min.	230	230	230	230	230
Palm Width (mm)	70±10	80±10	95±10	110±10	120±10
Thickness (mm) min.					
~ Finger	0.05	0.05	0.05	0.05	0.05
~ Palm	0.05	0.05	0.05	0.05	0.05
~ Cuff	0.04	0.04	0.04	0.04	0.04
Tensile Strength (MPa), min					
~ Unaged	16	16	16	16	16
~ Aged	16	16	16	16	16
Elongation (%), min					
~ Unaged	500	500	500	500	500
~ Aged	400	400	400	400	400

Single Use Only, Ambidextrous, Non-Sterile
Packaging: 300 gloves/box, 10 boxes/case; XL: 250 gloves/box

XS (3305) **M** (3307) **XL** (3309)
S (3306) **L** (3308)

Cranberry®

www.cranberryusa.com
like us on facebook.com/cranberryusa

Cranberry USA
828 San Pablo Avenue
Pinole, CA 94564
707-553-6190

PSB Singapore

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 22 Mar 2018.
2. For size XS, results for EN 455-2:2015 Clause 4 Dimensions is based on lot no. 03060511, while the rest of the results are based on lot no. 12150511.
3. Labelling requirements are assessed based on submitted packaging artwork together with client's declaration letter version number 2018003.
4. NA: Not applicable for the submitted sample.

Shareen Chan
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

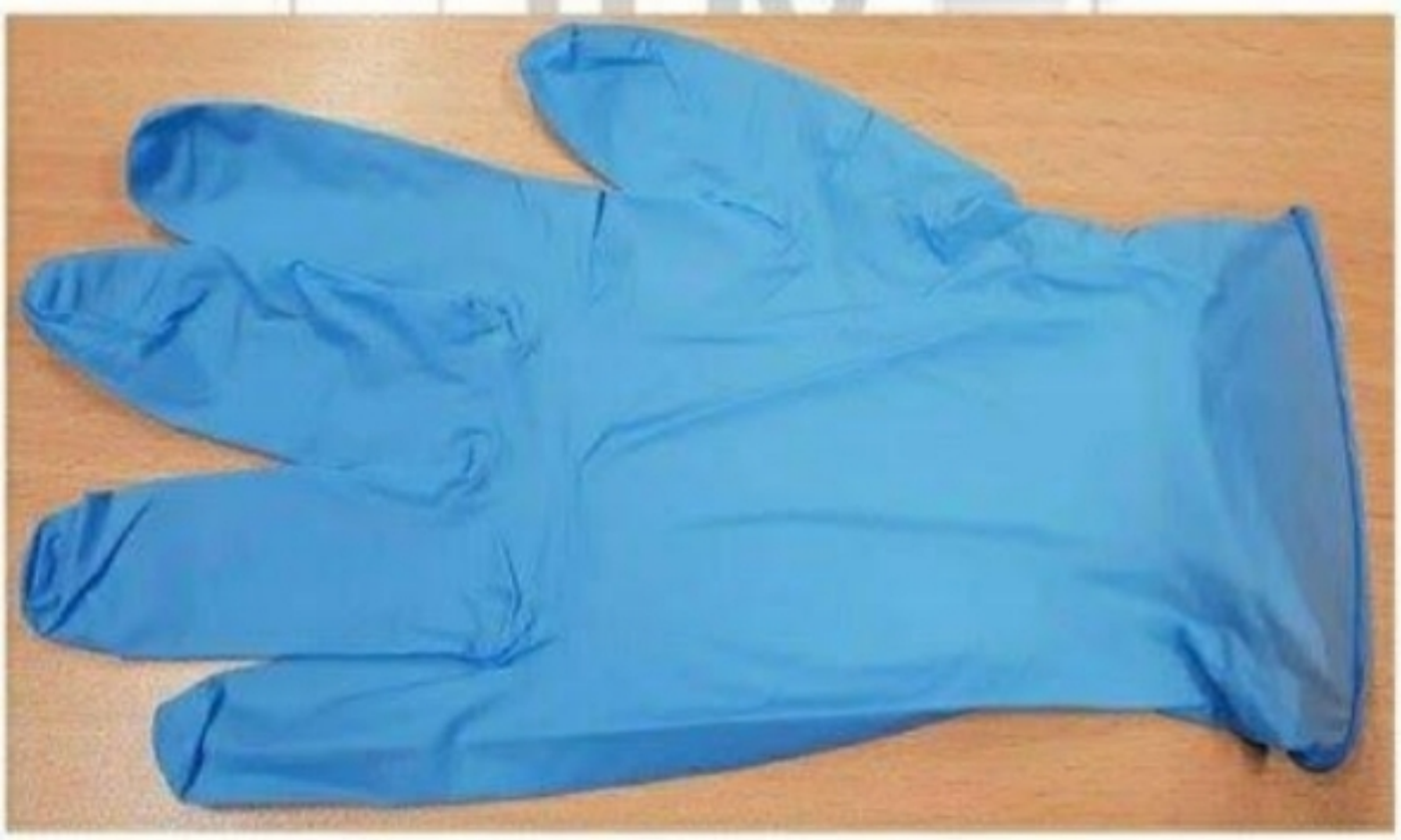


Photo : Powder Free Nitrile Examination Gloves, BS0002

RESULTS (cont'd):

Sample: Powder Free Nitrile Examination Gloves, BS0002

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 2018001		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	0.61 mg per glove	Passed
			S	0.63 mg per glove	Passed
			M	0.97 mg per glove	Passed
			L	0.86 mg per glove	Passed
			XL	0.48 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

Test Report No. 719 [redacted]
dated 23 Mar 2018

PSB Singapore

RESULTS:

Sample: Powder Free Nitrile Examination Gloves, BS0002

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	1	Passed
		S		10	315	1	Passed
		M		10	315	2	Passed
		L		10	315	6	Passed
		XL		10	315	4	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	250	Passed
		S		13	250	Passed
		M		13	255	Passed
		L		13	250	Passed
		XL		13	248	Passed
	b) Width (mm)	XS	≤ 80	13	73	Passed
		S	80 ± 10	13	85	Passed
		M	95 ± 10	13	96	Passed
		L	110 ± 10	13	106	Passed
		XL	≥ 110	13	115	Passed
5	Strength a) Force at break (N)	XS	For nitrile examination gloves: ≥ 6.0	13	6.4	Passed
		S		13	8.6	Passed
		M		13	6.1	Passed
		L		13	6.1	Passed
		XL		13	6.6	Passed
	b) Force at break after challenge testing (N)	XS	For nitrile examination gloves: ≥ 6.0	13	7.0	Passed
		S		13	9.0	Passed
		M		13	7.3	Passed
		L		13	6.6	Passed
		XL		13	7.1	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

Test Report No. 7191[redacted]
dated 23 Mar 2018

PSB Singapore

Choose certainty.
Add value.

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 [redacted]o., Ltd. on 25 Jan 2018 and 09 Mar 2018.

TESTED FOR:

[redacted]
[redacted]
[redacted]Shandong,
China.

TEST DATE:

26 Jan 2018 to 06 Feb 2018 and 22 Mar 2018

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Reference No.	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Examination Gloves	Blue	BS0002	12150511	XS	100	[redacted] Ltd.
				03060511		69	
				12150521	S	100	
				12080311	M	100	
				12090411	L	100	
				12070611	XL	407	

Lot size as specified by client: 200,000 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

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
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Singapore 118221

Phone : +65 6885 1333
Fax : +65 6776 8670
E-mail: enquiries@tuv-sud-psb.sg
www.tuv-sud-psb.sg
Co. Reg. : 199002664R

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

SATRA TECHNOLOGY

PPE REGULATION (EU) 2016/425
MODULE C2 CERTIFICATE

Issued to:

Blue Sail Medical Co Ltd
Qilu Chemical Industrial Park
No 21 Qingtian Road
Zibo
Shandong
China

This is to certify that the following products tested under SATRA reports referenced:CHM0291439/1944/JH & STE0289547 have been found to satisfy the requirement of PPE Regulation (EU) 2016/425 Module C2 EU quality control system for the final product for and on behalf of SATRA Technology Europe Limited

EU TYPE EXAMINATION CERTIFICATE NUMBER	PRODUCT GROUP REFERENCE	PRODUCT TYPE	CLASSIFICATION
2777/11521-01/E00-00	BS01020X	Disposable medical Nitrile examination glove	EN ISO 374-1:016

Dated: 14th November 2019

This certificate is valid until: November 2020

Signed By (Alan Weston)

For and on behalf of SATRA Technology Europe Limited

CE

The issuance of this certificate is subject to the company maintaining its manufacturing and quality system to the required standard.

SATRA Technology Europe Limited. Bracetown Business Park Clonee Dublin 15 D15 YN2P. Republic of Ireland.
(Notified Body number 2777)
Tel: +353 (0) 1 437 2484 Web: www.satraeutopo.com

510(k) Premarket Notification

Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K983334
Device Name	NITRILE POWDER FREE EXAMINATION GLOVES
Applicant	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Applicant Contact	Chong Yoon Tat
Correspondent	CRANBERRY (M) SDN. BHD. LOT 85, JALAN PORTLAND, TASEK INDUSTRIAL ESTATE Ipoh Perak, MY 31400
Correspondent Contact	Chong Yoon Tat
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	09/23/1998
Decision Date	02/19/1999
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

evolve 300

Nitrile Powder Free Examination Gloves

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