SUPÉRIEUR®

SIMPLY SUPERIOR

NITRILE POWDERLESS GLOVE

CONTENT

ABOUT US

PRODUCT SPECIFICATION

NITRILE GLOVES SPECS

POWDER FREE

Functional Benefits

- Protection from unwanted and dangerous substances
- Beaded cuff ensures easy donning and prevent roll down
- Superior strength with better puncture resistance
- Full textured or Finger Tip textured enhances wet and dry grip
- Thinner gauge improves tactile sensitivity
- Custom design enhances comfort and fit
- Provide an alternative solution for individuals who are allergic to natural rubber latex

Product Specifications

Material	Synthetic Nitrile latex.
Type	Non-Sterile Powder-Free. Ambidextrous; Finger Tip Textured; Beaded Cuff; White or Coloured (Blue, Light Blue, …)
Quality Standards	Conforms to ASTM D6319 Manufactured under ISO9001: 2008, ISO 13485:2003. ISO 22000:2005 Quality Management System. Manufactured from 100% nitrile (Acrylonitrile-Butadiene)
Gloves Size	Extra-small, Small, Medium, Large, Extra-large. Marked in the check box on the shipping carton with black ink.
Storage	Store in a dry and cool place, the temperature not higher than 38°C.
Shelf-fife	3 years from the date of manufacturing.

PHYSICAL DIMENSIONS

DIMENSIONS	**Standards**	
	ERBEN	**ASTM D6319**
Length (mm)	**230 min**	**220 min (XS, S)** **230 min (M, L, XL)**
Width (mm)	**75 ± 5 (XS)** **85 ± 5 (S)** **95 ± 5 (M)** **105 ± 5 (L)** **115 ± 5 (XL)**	**70 ± 10 (XS)** **80 ± 10 (S)** **95 ± 10 (M)** **110 ± 10 (L)** **120 ± 10 (XL)**
Thickness-Single wall (mm)	**Fingers : 0. 08 mm min** **Palm : 0.06 mm min**	**Fingers : 0.050 mm min** **Palm : 0.05 mm min**

PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

Tensile	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min Elongation at break (%) Before aging: 600% min After aging: 500% min	Tensile strength (MPA) Before aging: 14Mpa min After aging: 14Mpa min Elongation at break (%) Before aging: 500% min After aging: 400% min
Powder Content	2 mg/glove maximum	
Protein Content	Free Protein	

Minimum Standard of Glove **Specification:**

MATERIAL	CUFF THICKNESS	PALM THICKNESS	FINGER THICKNESS	LENGTH	WIDTH meaning Circumference (MM)
Nitrile: 100% Latex Free and DEHP Free	3.3 mil +/- 0.5 mil	4.25 mil +/- 0.5 mil	5.3 mil +/- 0.5 mil	9.65" +/-0.25"	177.8 (XS) 203.2 (S) 228.6 (M) 254 (L) 279.4 (XL) 304.8 (XXL)
	0.084mm +/- 0.013mm	0.108mm +/- 0.013mm	0.135mm +/- 0.013mm	240mm	

- 100% Nitrile disposable gloves,
- Colour preference blue,
- 100 (One Hundred) gloves/pieces per box;
- Latex free, powder free;
- Silicone free chlorinated;
- Rolled cuff;
- EN455 standard; ISO
- CE Conformity; and
- FDA 510(k).

Nitrile Examination Gloves

Product Information

Disposable Nitrile Examination Gloves, Powder Free, Non-sterile

Primary Material	:	Acrylonitrile Butadiene Synthetic Rubber Latex
Latex Protein Content	:	Latex-free
Color	:	White/ Black/ Blue
Size	:	Extra-small, Small, Medium, Large And Extra-large
Design And Feature	:	Ambidextrous, Straight Fingers, Finger-textured, Beaded Cuff, Polymer Coated/ Online Chlorinated
Packing	:	100 Pieces Gloves Per Dispenser, 10 Dispensers Per Carton

Medical Use

Food Contact Use

General Use

Physical Dimensions

Dimensions		Standards	
		Supérieur	ASTM D6319 / EN 455
Length (mm)		240 min	230 min / 240 min
Width (mm)	Extra-Small	75 ± 10	75 ± 10
	Small	80 ± 10	80 ± 10
	Medium	95 ± 10	95 ± 10
	Large	110 ± 10	110 ± 10
	Extra-large	≧ 110	≧ 110
Thickness-single wall (mm)	Palm	Min. 0.05	Min. 0.05
	Finger	Min. 0.05	Min. 0.05

Physical Properties

Criteria		Supérieur	ASTM D6319 / EN 455
Elongation (%)	Before Aging	Min. 500	Min. 500
	After Aging	Min. 400	Min. 400 / Min. 500
Tensile Strength	Before Aging	Min. 18 (MPa)	Min. 14 (MPa) / 6.0 N
	After Aging	Min. 14 (MPa)	Min. 14 (MPa) / 6.0 N

Manufactured under ISO 9001 & ISO 13485 Quality Systems

PACKAGING SPECIFICATION

SIMPLY SUPÉRIEUR

1. NITRILE EXAM GLOVE POWDER FREE

Product Name	Nitrile Exam Gloves Powder Free	
Place of Origin	Manufatured in Vietnam	
Material	100% Nitrile (synthetic rubber)	
Application	Medical use, food contact use, general use etc	
Brand Name	Simply Supérieur (Ever Global Vietnam Group)	
Size	XS, S, M, L, XL (size is marked on the box)	
Type	Disposable, Powder Free. Use for both hands, surface of rough of fingertips, car wrist trim.	
Color	Blue / Black / White	
Weight	3.0g/3.5g/4.0g/4.5g	
Standard	FDA 510K, CE, EN ISO 374-5:2016, EN420:2003+A1:2009, EN374-1:2016	
Packing Detail	100pcs/box, 10 boxes/carton, 1000pcs/carton	
Supply Ability	5,000,000 cartons/month	
Minimum Order	100,000 cartons	
Specification for Carton	Size	360x260x240 mm
	Weight	~4kg/carton

FDA CERTIFICATION

September 6, 2019

Ever Global (Vietnam) Enterprise Corporation
% Albert T.w. Li
Official Third Party Correspondent
Center For Measurement Standards Of Industrial
Bldg. 16, 321 Kuang Fu Rd,sec2
Hsinchu, Tw

Re: K190403
Trade/Device Name: Disposable Powder Free Nitrile Examination Glove, White Color, Tested for Use With Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drug
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-powdered patient examination glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: August 27, 2019
Received: September 3, 2019

Dear Albert T.w. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam

Tel: 84-61-3514022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190403

Device Name

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min)
1. Carmustine (BCNU), 3.3 mg/ml	6.2
2. Thiotepa, 10.0 mg/ml	38.8
3. Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
4. Cisplatin, 1.0 mg/ml	≥ 240
5. Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
6. Fluorouracil, 50.0 mg/ml	≥ 240
7. Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
8. Etoposide (Toposar), 20.0 mg/ml	≥ 240
9. Paclitaxel (Taxol), 6.0 mg/ml	≥ 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	6.2 minutes
Thiotepa, 10.0 mg/ml	38.8 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Tel: 84-61-3514022

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190403

Device Name
Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs

Indications for Use *(Describe)*

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min)
1. Carmustine (BCNU), 3.3 mg/ml	22.8
2. Thiotepa, 10.0 mg/ml	54.6
3. Cyclophosphamide (Cytoxan), 20.0 mg/ml	≥ 240
4. Cisplatin, 1.0 mg/ml	≥ 240
5. Doxorubicin Hydrochloride, 2.0 mg/ml	≥ 240
6. Fluorouracil, 50.0 mg/ml	≥ 240
7. Dacarbazine (DTIC), 10.0 mg/ml	≥ 240
8. Etoposide (Toposar), 20.0 mg/ml	≥ 240
9. Paclitaxel (Taxol), 6.0 mg/ml	≥ 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time

Carmustine (BCNU), 3.3 mg/ml	22.8 minutes
Thiotepa, 10.0 mg/ml	54.6 minutes

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ever Global (Vietnam) Enterprise Corporation

No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Tel:84-61-3514022

510(k) SUMMARY

K190403

Premarket Notification [510(k)] Summary

1.0 Submitter:

Submitter's name :	Ever Global (Vietnam) Enterprise Corporation
Submitter's address :	No. 1 Road, Long Thanh Industrial Zone, Taman Village, Long Thanh District, Dong Nai Province, Vietnam
Phone number :	84-61-3514022
Fax number :	84 -61-3514023
Name of contact person:	Jerry Lin
Summary Preparation Date:	September 6, 2019

2.0 Name of the Device

Proprietary/Trade name:	Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs, Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs
Common Name:	Nitrile Examination Gloves
Classification Name:	Patient Examination Glove
Device Classification:	Class I
Regulation Number:	21 CFR 880.6250
Product Code:	LZA, LZC

3.0 Predicate device

Device Name:	KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black)
Company name:	Koon Seng Sdn. Bhd.
510(K) Number:	K171171

4.0 Device Description:

Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs is a patient examination glove made from nitrile compound, non-sterile (as per 21 CFR 880.6250, Class I). The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

5.0 Indication for use:

Disposable Powder Free Nitrile Examination Glove, White Color, Tested For Use With Chemotherapy Drugs

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Table 5.1 Nitrile white color test for 9 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1.	Carmustine (BCNU), 3.3 mg/ml	22.8
2.	Thiotepa, 10.0 mg/ml	54.6
3.	Cyclophosphamide (Cytoxan), 20.0 mg/ml	2 240
4.	Cisplatin, 1.0 mg/ml	2 240
5.	Doxorubicin Hydrochloride, 2.0 mg/ml	2 240
6.	Fluorouracil, 50.0 mg/ml	2 240
7.	Dacarbazine (DTIC), 10.0 mg/ml	2 240
8.	Etoposide (Toposar), 20.0 mg/ml	2 240
9.	Paclitaxel (Taxol), 6.0 mg/ml	2 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	22.8 minutes
Thiotepa, 10.0 mg/ml	54.6 minutes

Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy Drugs

A patient examination gloves is a disposable device intended for medical purpose that is worn on the examiner's hand or fingers to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:

Table 5.2 Nitrile blue color test for 9 chemotherapy drugs

	Test Chemotherapy Drug and Concentration	Minimum Breakthrough Detection Time (Min.)
1.	Carmustine (BCNU), 3.3 mg/ml	6.2
2.	Thiotepa, 10.0 mg/ml	38.8
3.	Cyclophosphamide (Cytoxan), 20.0 mg/ml	2 240
4.	Dacarbazine (DTIC), 10.0 mg/ml	2 240
5.	Doxorubicin Hydrochloride, 2.0 mg/ml	2 240
6.	Etoposide (Toposar), 20.0 mg/ml	2 240
7.	Fluorouracil, 50.0 mg/ml	2 240
8.	Paclitaxel (Taxol), 6.0 mg/ml	2 240
9.	Cisplatin, 1.0 mg/ml	2 240

The maximum testing time is 240 minutes. Please note that the following drug has an extremely low permeation time:

Carmustine (BCNU), 3.3 mg/ml	6.2 minutes
Thiotepa, 10.0 mg/ml	38.8 minutes

6.0 Technological Characteristics:

Shown below is a technological comparison of the subject device(K190403) with the predicate device (K171171)

Device Characteristic	**Predicate Device (K171171)**	**Proposed Device (K190403)**	Comparison
Product name	KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black)	Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs	N/A
510(K) No.	K171171	K171422	N/A
Product Owner	Koon Seng Sdn. Bhd.	Ever Global Enterprise Corporation	Different
Product Code	LZA, LZC	LZA, LZC	same
Regulation	21 CFR 880.6250	21 CFR 880.6250	same
Class	I	I	same
Intended Use	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	similar
Power free	Yes	Yes	same
Size	Small/ Medium/Large/X Large	Small/ Medium/Large/X Large	same
Single Use	YES	YES	same
Non-Sterile	YES	YES	same
Dimensions-Length	Complies with ASTM D6319-10 230 mm min.	Complies with ASTM D6319-10 230 mm min.	same

Dimensions -Palm Width	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	same
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.07 mm min. Finger - 0.08 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min. *{Additional comparisons a device - K171104, that have been approved by FDA is the same intended use and the thickness is lower than Proposed Device)*	similar

Intended Use	A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	The Nitrile Powder Free patient examination glove is a non-sterile disposable device intended for medical purposes that is worn on the examiner's hands or finger to prevent contamination between patient and examiner. In addition, these gloves were tested for use with chemotherapy drugs in accordance with ASTM D6978-05 Standard Practice for Assessment of Medical gloves to Permeation by Chemotherapy Drugs:	similar
Power free	Yes	Yes	same
Size	Small/ Medium/Large/X Large	Small/ Medium/Large/X Large	same
Single Use	YES	YES	same
Non-Sterile	YES	YES	same
Dimensions- Length	Complies with ASTM D6319-10 230 mm min.	Complies with ASTM D6319-10 230 mm min.	same
Dimensions -Palm Width	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	Complies with ASTM D6319-10 Small 80±10 Medium 95 ±10 Large 110±10 X large 120 ±10	same
Dimensions -Thickness	Complies with ASTM D6319-10 Palm - 0.07 mm min. Finger - 0.08 mm min.	Complies with ASTM D6319-10 Palm - 0.05mm min. Finger - 0.05 mm min. *{Additional comparisons a device - K171104, that have been approved by FDA is the same intended use and the thickness is lower than Proposed Device)*	similar
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10 Dermal sensitization in the guinea pig ISO 10993-10 /	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01 Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01 Minimal Essential Media (MEM) Elution ISO 10993-5	similar

7.0 Summary of Non-Clinical Performance Data:

Shown below are the results from the bench testing performed on the subject devices. The testing was performed to

demonstrate the subject devices met the acceptance criteria for each of the non-clinical test shown below: Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs are summarized with the following technological characteristics compared to ASTM or equivalent standard.

Table 7.1 Summary of the Non-Clinical Testing

Characteristics	Standard		
Dimension	ASTM standard D 6319-10(Reapproved 2015)		
	Length	2230mm	
	Width	Small	80 ±10 mm
		Medium	95 ±10 mm
		Large	110 ±10 mm
		X large	120 ±10 mm
	Thickness	Finger tip	20.05mm
		Palm	20.05mm
Physical Properties	ASTM standard D 6319-10(Reapproved 2015)		
	Tensile strength (Before aging)		214MPa
	Tensile strength (After aging)		214MPa
	Elongated rate (Before aging)		2500%
	Elongated rate (After aging)		2400%
Freedom from pinholes	21 CFR 800.20 ASTM standard D 6319-10(Reapproved 2015) Test method in accordance with ASTM D5151-06(Reapproved 2015)		Passed Standard Acceptance Criteria
Powder Residual	ASTM standard D6319-10(Reapproved 2015) Test method in accordance with D6124-06(Reaffirmation 2011)		< 2 mg/glove
Biocompatibility	Primary Skin Irritation in rabbits ISO 10993-10: Third Edition 2010-08-01	Passes Under the conditions of the study, the subject device is not a primary skin irritant.	
	Dermal sensitization in the guinea pig ISO 10993-10: Third Edition 2010-08-01	Passes Under the conditions of the study, the subject device is not a primary skin sensitizer.	
	Minimal Essential Media (MEM) Elution ISO 10993-5	Passes Under the conditions of the study, the subject device is not cytotoxic.	

- ✡ Dimension per ASTM D6319-10 (Reapproved 2015)
- ✡ Tensile strength (Before aging/After aging) and Elongation (Before aging/After aging) per ASTM D6319-10(Reapproved 2015)
- ✡ Water leak test on pinhole per ASTM D6319-10(Reapproved 2015) and per 21 CFR 800.20.
- ✡ Powder Residual tests per ASTM D6319-10(Reapproved 2015)
- ✡ Biocompatibility test per ISO 10993-10: Third Edition 2010-08-01 and ISO 10993-5
- ✡ Assessment of Resistance To Permeation By Chemotherapy Drugs per ASTM D6978-05(R 2013)

8.0 Summary of Clinical Test:

Clinical data was not needed for this device.

9.0 Conclusion:

Based on the nonclinical tests data, it can be concluded that the Disposable Powder Free Nitrile Examination Glove, White/Blue Color, Tested For Use With Chemotherapy Drugs is as safe, as effective, and performs as well as or better than the predicate device K171171, KS Medicare Powder Free Nitrile Examination Gloves, Non-sterile, Tested for Use with Chemotherapy Drugs (Blue, Black), by Koon Seng Sdn. Bhd.

CE CERTIFICATION

EMERGO EUROPE

CE Registration Certificate

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received Medical Device Registrations on the following date:

26 May 2009
See attached product listing

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the Medical Devices fulfill the applicable requirements of Directive 93/42/EEC.

June 2009

Rene van de Zande
President & CEO
Emergo Europe

VALID CE CERTICATION WILL BE GIVEN UPON DEPOSIT AND SIGNING AGREEMENT

EmergoEurope.com

EU DECLARATION OF CONFORMITY

2F, No. 68, Sec. 1, Neihu Rd., Neihu Dist., Taipei 11493, Taiwan
TEL : +886-2-6606-6688 · FAX : +886-2-6606-1818
E-mail : sales@pmgloves.com
www.pmgloves.com

EU Declaration of Conformity

We, **PRECIOUS MOUNTAIN ENT. CORP.,** hereby declares that the following Personal Protective Equipment (PPE).

1. Model & Description ■ GNP (Disposable Nitrile Gloves, Powdered)
   ■ GNF (Disposable Nitrile Gloves, Powder-free)
2. Glove sizes XS, S, M, L, XL or 6, 7, 8, 9, and 10
3. Manufacturer **PRECIOUS MOUNTAIN ENT. CORP.**
   2F No.68, Sec 1., Neihu rd., Neihu Dist., Taipei City 114, Taiwan
   P. 886-2-6606-6688 P. 886-2-6606-1818
4. Classification Category III-Complex
5. It is in conformance with the Regulation (EU) No 2016/425 of the European Parliament and of the Council and national standards in some cases, in conformance with the harmonized standards conversion.
6. The notified body SATRA (Number: 2777) performed the EU type-examination certificate number is_____ (Module B).
7. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation: EN420:2003+A1:2009, EN374-1:2016, EN ISO 374-5:2016.
8. Europe Standard
   - ✓ EN ISO 374-1:2016,
   - ✓ EN 374-2: 2014
   - ✓ EN 16523-1 :2015
   - ✓ EN 420:2003+A1:2009
   - ✓ EN ISO 374-4:2013
   - ✓ EN ISO 374-5:2016,

For and on behalf of
PRECIOUS MOUNTAIN ENT. CORP.

Tammy Phone / Quality Manager
Date: Nov. 09, 2018

TEST REPORT

Test Report

No. : CT/2018/70053C Date : 2018/09/18

PRECIOUS MOUNTAIN ENT. CORP
2F., NO. 68, SEC. 1, NEIHU RD., NEIHU DIST., TAIPEI, TAIWAN

The following sample(s) was/were submitted and identified by/on behalf of the applicant as :

Sample Submitted By	:	PRECIOUS MOUNTAIN ENT. CORP
Sample Description	:	DISPOSABLE NITRILE GLOVES (BLUE)
Style/Item No.	:	LOT#HL12050401
Sample Material	:	NBR(N300ITRILE)
Sample description(Item No.) of the same material	:	DISPOSABLE NITRILE GLOVES (BLACK/WHITE/VIOLET)
Sample Receiving Date	:	2018/07/03
Testing Period	:	2018/07/03 TO 2018/08/02 AND 2018/07/19 TO 2018/08/02 AND 2018/08/16 TO 2018/08/27

==========

Test Requested : As specified by client, the sample(s) was/were tested with reference to Resolution (EC) No 1935/2004, Council of Europe Resolution ResAP(2004)4. Please refer to result table for testing item(s).

Test Result(s) : Please refer to following pages.

* This report is added testing and combined with CT/2018/70053 *

Singh Hsiao / Supervisor
Signed for and on behalf of
SGS TAIWAN LTD.
Chemical Laboratory - Taipei

PRECIOUS MOUNTAIN ENT. CORP
2F., NO. 68, SEC. 1, NEIHU RD., NEIHU DIST., TAIPEI, TAIWAN

Test Result(s)

PART NAME No.1 : BLUE RUBBER GLOVE

PASS

Test Item(s)	Unit	Method	MDL	Result No.1	Limit
Overall migration (3% Acetic Acid)	mg/dm²	With reference to EN 1186 (2002). (70°C, 2 hrs)	3.0	7.83	10
Overall migration (10% Ethanol)	mg/dm²		3.0	9.50	10
Overall migration (Rectified Olive Oil)	mg/dm²		3.0	n.d.	10
Nitrosamines					
N-nitrosodimethylamine (CAS No.: 62-75-9)	mg/kg	With reference to EN 14350 (2004). Analysis was performed by GC/MS.	0.01	n.d.	0.01
N-nitrosodiethylamine (CAS No.: 10595-95-6)	mg/kg		0.01	n.d.	0.01
N-nitrosomethylethylamine (CAS No.: 55-18-5)	mg/kg		0.01	n.d.	0.01
N-nitrosodipropylamine (CAS No.: 621-64-7)	mg/kg		0.01	n.d.	0.01
N-nitrosomorpholine (CAS No.: 59-89-2)	mg/kg		0.01	n.d.	0.01
N-nitrosopyrrolidine (CAS No.: 930-55-2)	mg/kg		0.01	n.d.	0.01
N-nitrosopiperidine (CAS No.: 100-75-4)	mg/kg		0.01	n.d.	0.01
N-nitrosodibutylamine (CAS No.: 924-16-3)	mg/kg		0.01	n.d.	0.01
N-nitrosodiphenylamine (CAS No.: 86-30-6)	mg/kg		0.01	n.d.	0.01
Methylphenylnitrosamine (CAS No.: 614-00-6)	mg/kg		0.01	n.d.	0.01
Ethylphenylnitrosamine (CAS No. 612-64-6)	mg/kg		0.01	n.d.	0.01
N-nitrosodibenzylamine (CAS No.: 5336-53-8)	mg/kg		0.01	n.d.	0.01
Nitrosatable					
N-nitrosodimethylamine	mg/kg	With reference to EN 14350 (2004). Analysis was performed by GC/MS.	0.1	n.d.	0.1
N-nitrosodiethylamine	mg/kg		0.1	n.d.	0.1
N-nitrosomethylethylamine	mg/kg		0.1	n.d.	0.1
N-nitrosodipropylamine	mg/kg		0.1	n.d.	0.1
N-nitrosomorpholine	mg/kg		0.1	n.d.	0.1
N-nitrosopyrrolidine	mg/kg		0.1	n.d.	0.1
N-nitrosopiperidine	mg/kg		0.1	n.d.	0.1
N-nitrosodibutylamine	mg/kg		0.1	n.d.	0.1
N-nitrosodiphenylamine	mg/kg		0.1	n.d.	0.1
Methylphenylnitrosamine	mg/kg		0.1	n.d.	0.1
Ethylphenylnitrosamine	mg/kg		0.1	n.d.	0.1
N-nitrosodibenzylamine	mg/kg		0.1	n.d.	0.1

Test Report

No. : CT/2018/70053C Date : 2018/09/18

PRECIOUS MOUNTAIN ENT. CORP
2F., NO. 68, SEC. 1, NEIHU RD., NEIHU DIST., TAIPEI, TAIWAN

Test Item(s)	Unit	Method	MDL	Result	Limit
				No.1	
Specific migration of Primary Aromatic Amine (PAA)	mg/kg	With reference to EN 13130-1 (2004) and BfR recommendation XXI. Analysis was performed by UV-vis Spectrophotometer. (3% acetic acid, 70°C, 2 hrs)	0.002	n.d.	0.01 (▲1)

Remark :

- (▲1) : Limit is according to Council of Europe Resolution AP (2004) 4.

Note :

1. mg/kg = ppm ; mg/dm² = milligram per square decimeter
2. MDL = Method Detection Limit
3. n.d. = Not Detected = below MDL
4. ℃ = degree Celsius
5. Test condition & simulant were specified by client.
6. This report supersedes the previous document bearing the test report number CT/2018/70053A.

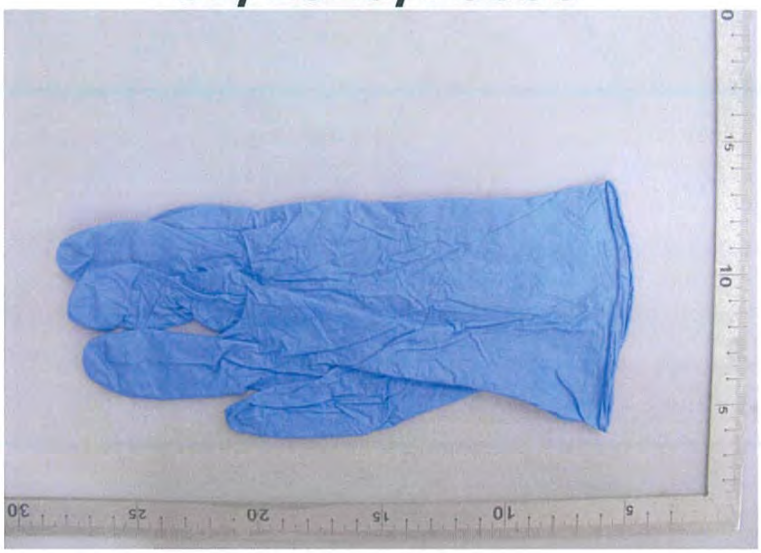
Test Report

No. : CT/2018/70053C Date : 2018/09/18

PRECIOUS MOUNTAIN ENT. CORP
2F., NO. 68, SEC. 1, NEIHU RD., NEIHU DIST., TAIPEI, TAIWAN

*** The tested sample / part is marked by an arrow if it's shown on the photo. ***

CT/2018/70053



** End of Report **

ISO 13485:2016 & 9001:2015

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 098755 0002 Rev. 00

Holder of Certificate: **Ever Global (Vietnam) Ent. Corp - Giang Dien Factory**
No 9 Street, Giang Dien Industrial Park
Trang Bom District
Dong Nai Province
VIETNAM

Facility(ies): Ever Global (Vietnam) Ent. Corp - Giang Dien Factory
No 9 Street, Giang Dien Industrial Park, Trang Bom District, Dong Nai Province, VIETNAM

Certification Mark:

Scope of Certificate: **Manufacturing and sales of powdered and powder free synthetic vinyl gloves and powder free nitrile gloves for medical use**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: VIE201802

Valid from: 2018-07-26
Valid until: 2020-05-14

Date, 2018-07-26

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Ever Global (Vietnam) Ent. Corp - Giang Dien Factory

No 9 Street, Giang Dien Industrial Park, Trang Bom District,
70000 Dong Nai Province
Vietnam

has established and applies
a Quality Management System for

Manufacturing and sales of
powdered and powder free synthetic vinyl gloves
and powder free nitrile gloves for medical use.

An audit was performed, Report No. **707077466.**

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2018-08-10** until **2020-07-23.**

Certificate Registration No.: **12 100 54329 TMS.**

Product Compliance Management
Munich, 2018-08-13

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-03/2018

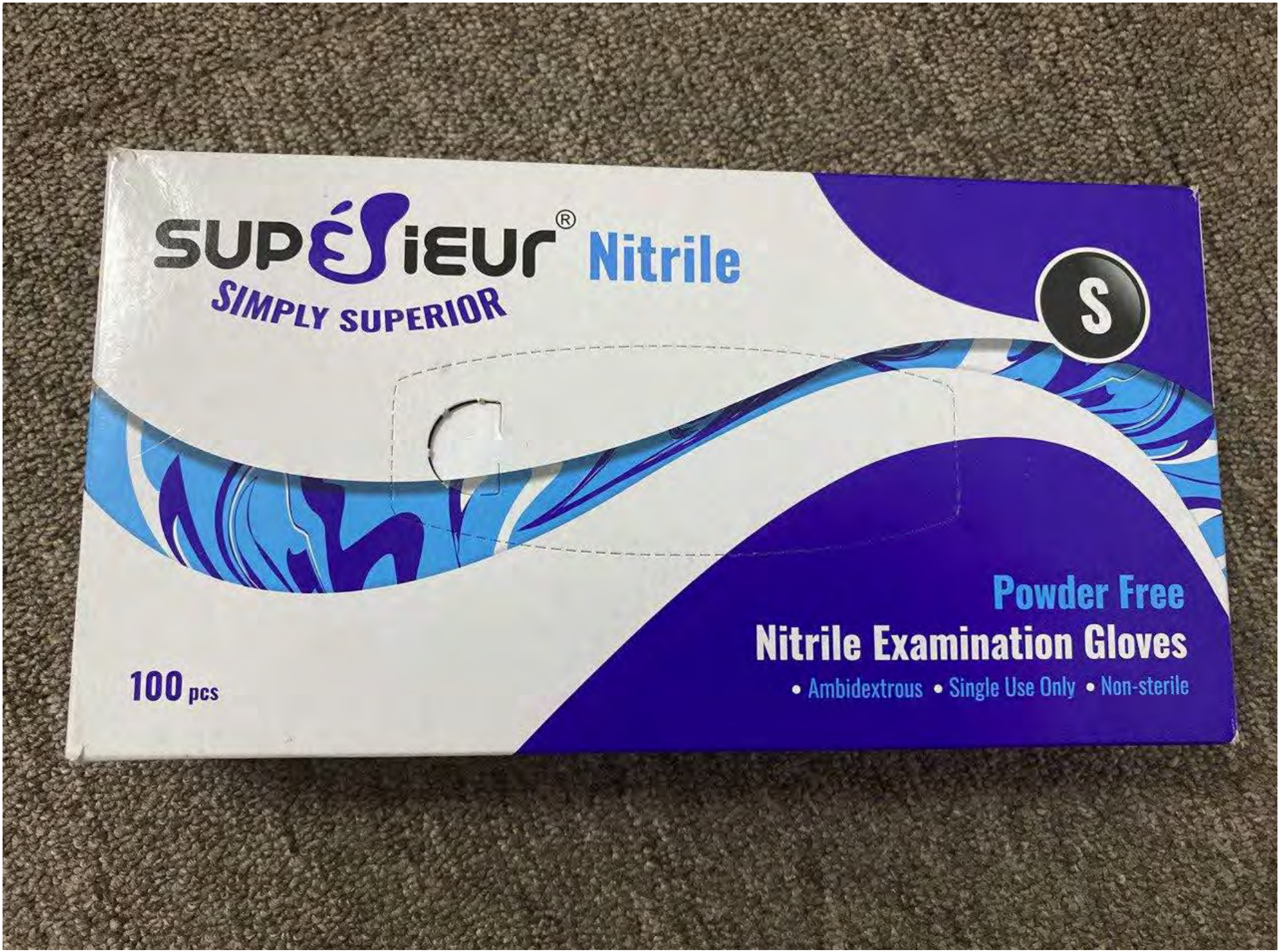
GLOVE AND PACKAGING IMAGE


XS
Powder Free
Nitrile Examination Gloves
Nitrile
M
SUPÉRIEUR® Nitrile
SIMPLY SUPERIOR
100 PCS
XL
S
L
SUPÉRIEUR
SIMPLY SUPERIOR®


L
Powder Free
Nitrile Examination Gloves
100 pcs
SUPÉRIEUR


SUPÉRIEUR®
SIMPLY SUPERIOR
Nitrile
Examination Gloves
L
• Powder Free • Ambidextrous • Single Use Only • Non-sterile
10 Boxes
100 Per Box
30°C
10°C
Blue
Black
White
EVER GLOBAL (VIETNAM) ENTERPRISE CORP.
Made in Vietnam


SUPÉRIEUR®
SIMPLY SUPERIOR
Nitrile
S
Gloves
• Single Use Only • Non-sterile


SUPÉRIEUR®
SIMPLY SUPERIOR
Nitrile
S
Powder Free
Nitrile Examination Gloves
• Ambidextrous • Single Use Only • Non-sterile
100 pcs

SUPÉRIEUR®

Nitrile Examination Gloves

Powder free, Non-sterile, Ambidextrous.
Free from natural rubber latex.
Nitrile Butadiene Rubber

Storage : Protect from heat, humidity, strong light and ozone.

LOT 20200213

022020

022024

Made in Vietnam

EVER GLOBAL (VIETNAM) ENTERPRISE CORPORATION
Address : Route 1, Long Thanh Industrial Zone, Long Thanh District, Dong Nai Province, 76211, Vietnam
E-mail : info@egvnco.com
TEL : 0251-8966-677
License No. : 190000024/PCBA-ĐN 180000010/PCBSX-ĐN
Item No. : NBR027

CE

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8 936186 380273


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