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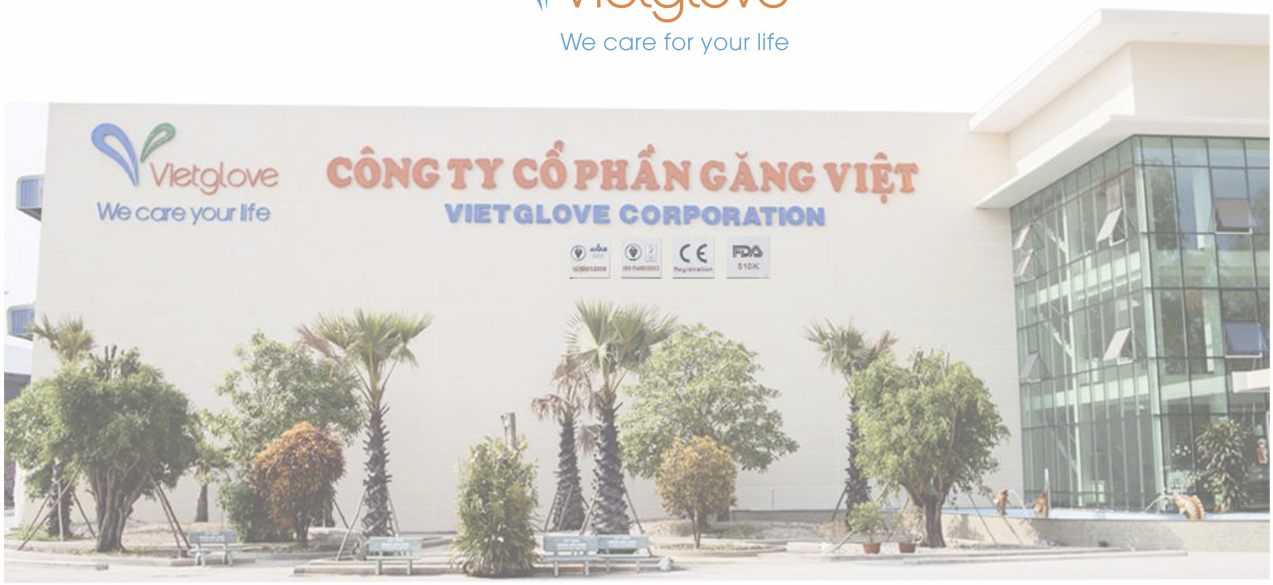
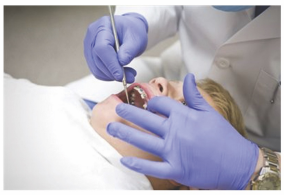


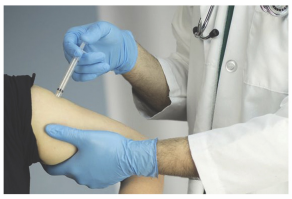
LEADING GLOVE MANUFACTURER IN VIETNAM

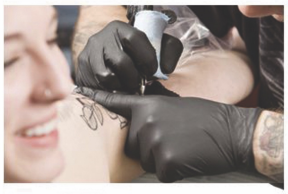
VIETGLOVE CORPORATION

NITRILE/LATEX EXAMINATION GLOVE

Non-Sterile | Ambidextrous | Powdered | Powder Free







CE

bsi. ISO 13485:2016 Medical Device Quality Management

bsi. ISO 9001:2015 Quality Management

FDA

GOOD MANUFACTURING PRACTICE GMP

Food Safety System Certification 22000

PRODUKTSICHERHEIT ISEGA MIT BRIEF UND SIEGEL

ETHICALLY CORRECT CERTIFIED COMPANY SA 8000

BSCI Business Social Compliance Initiative

Commitment to Quality Producing
Reliable Consistent Quality Gloves

www.vietglove.vn

OVERVIEW FACTORY
TỔNG QUAN NHÀ MÁY

Name Tên nhà máy	Vietglove Corporation Công TY CP Găng Việt
Active time ***Thời gian hoạt động***	In 2015 Năm 2015
Production line ***Đường line sản xuất***	10 double lines Công Nghệ 10 line đôi
Capacity ***Năng Lực sản xuất***	170.000.000pcs/month 170.000.000pcs/ tháng
Workforce ***Lực Lượng Công nhân viên***	600 staffs 600 công nhân viên

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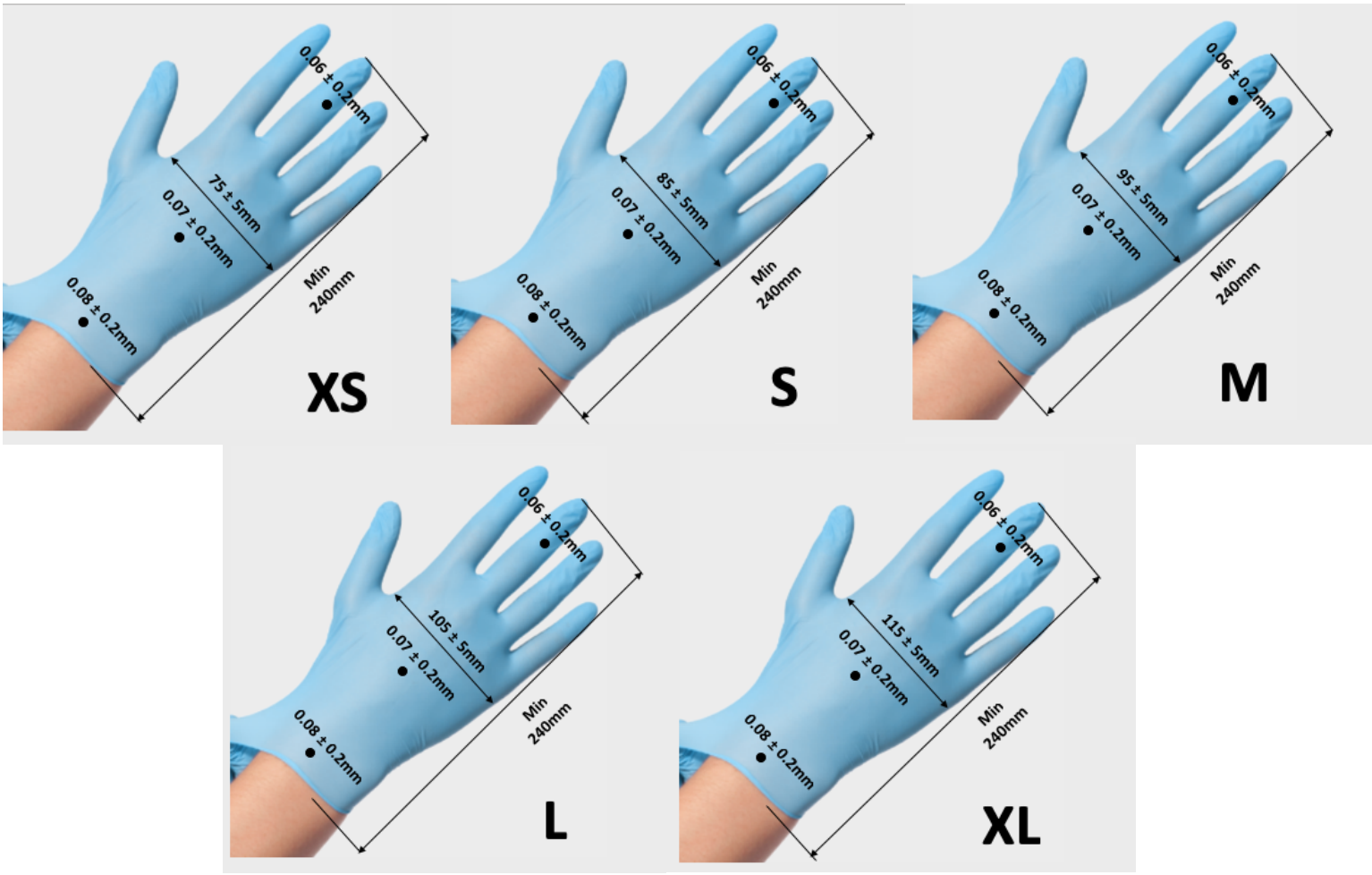
RANGE OF PRODUCT
LOẠI HÌNH SẢN PHẨM

Nitrile Powder Free Examination Gloves/Găng tay khám không bột Loại Nitrile Finger Texture – 240 mm/ Nhám ngón tay- chiều dài 240mm					
Weight Trọng Lượng (+/- 0.2 gr)	3.0 gr	3.5 gr	4.0 gr	4.5 gr	5.0 gr
Palm thickness Độ dày lòng bàn tay (+/- 0.02 mm)	0.06 mm	0.07 mm	0.08 mm	0.09 mm	0.10 mm

Description specification of the product/Mô tả tiêu chuẩn kỹ thuật của sản phẩm



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PRODUCT SPECIFICATION

EN - NT3.5

Product Name	**Powder Free Nitrile Examination Gloves**		
Type	Single Use Non- sterile Powder Free Nitrile Medical Examination Gloves		
Design and Feature	Ambidextrous, straight fingers, finger textured, beaded cuff		
Color	Blue, White, Black, Violet Blue		
Average Weight of Medium Size	3.5 gm (± 0.2gm)		
Material	Nitrile (Carboxylated Butadiene Acrylonitrile)		
Usage	To conduct medical examination, diagnostic and therapeutic procedures to protect patient and user from cross contamination or infection.		
Storage Condition	The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight		
Shelf life	The gloves shall have shelf life of 05 years from the date of manufacture with the above storege condition.		
Product Characteristic:			
Dimension	Size	Palm Width (mm)	Length (mm)
	X- Small	75 ± 5mm	240min
	Small	85 ± 5mm	240min
	Medium	95 ± 5mm	240min
	Large	105 ± 5mm	240min
	Extra Large	115 ± 5mm	240min
Thickness	Single wall thickness (mm)		
	Cuff	0.06 ± 0.02	
	Palm	0.07 ± 0.02	
	Finger	0.08 ± 0.02	
Physical Properties (EN Standard)		Un-aged	Aged
	Force at break (N)	Average Min 5.5	Average Min 5.5
Residual Powder	2.0 mg/glove maximum		
Total protein	no present		
Weight (gr)	X- Small	2.9 ± 0.2	
	Small	3.2 ± 0.2	
	Medium	3.5 ± 0.2	
	Large	3.8 ± 0.2	
	Extra Large	4.1 ± 0.2	
Quality Specfication			
Quality Specfication *AND - Accept No Defects *n - number of samples		In-House Standard	EN 455 Standard
	Inspection Criteria	Sampling Plan/ AQL	Sampling Plan/ AQL
	Dimension	S2 - AQL 4.0	13 pcs (Median)
	Force at break	S2 - AQL 4.0	13 pcs (Median)
	Water Tight Test	G1 - AQL 1.5	G1 - AQL 1.5
	Visual Inpection- Major	G1- AQL 2.5	G1 - AQL 2.5
	Visual Inpection- Minor	G1- AQL 4.0	G1 - AQL 4.0
	Residual Powder	n = 5 (Average)	n = 5 (Average)
	Packaging Labeling	n = 6 (AND)	n = 5 (AND)
	Glove Physical Counting	S2 - AQL 4.0	n = 5 (AND)
Packaging Configuration and Labeling:			
Packing	100/200 Gloves per Inner Dispenser (by weight) 10/20 Dispensers per Outer Carton		
Size Marking	The size of gloves shall be mark in the check box on every carton with black ink		
Labeling	The dispensers and outer cartons shall have the following information/ prints: Product description and Brand including size and net quantily of gloves. Name and Country of Orgin of Manufacturer or Distributor. Single Use Only or the Symbol for single use.		
Lot Numbering System	Per the customer's requirement or in house as per SOR. Manufacturing and/or expiry date where applicable.		

Prepare by

QA manager
Date: 01/01/2019

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RANGE OF COLOR
MÀU SẮC SẢN PHẨM

Light Blue/Xanh Nhạt

Medium Blue/Xanh

Violet Blue/ Tím

1
2
3
4
5

Black/Đen

White/Trắng

PICTURES OF PRODUCT
HÌNH ẢNH SẢN PHẨM

Mặt trước/Front view

Mặt sau/Back view

Mặt dưới/Bottom

Mặt trên/Top

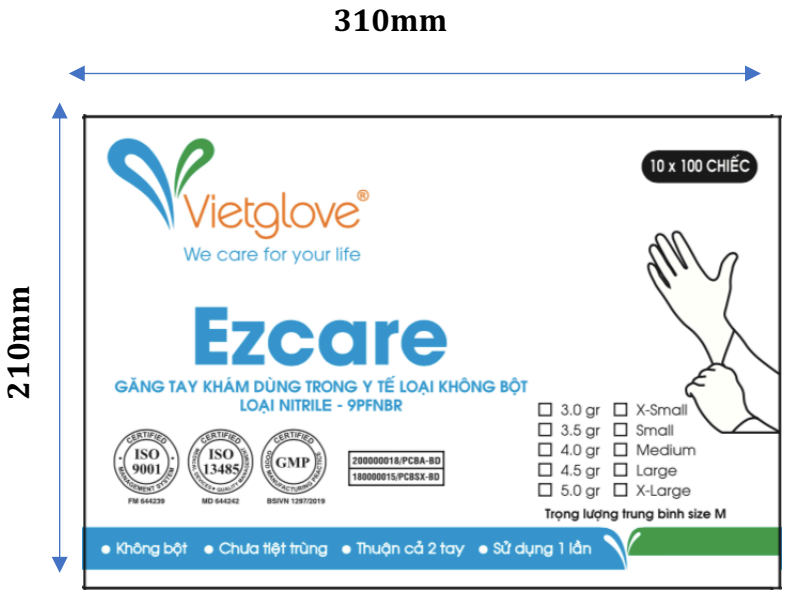
Mặt hông/ Side face

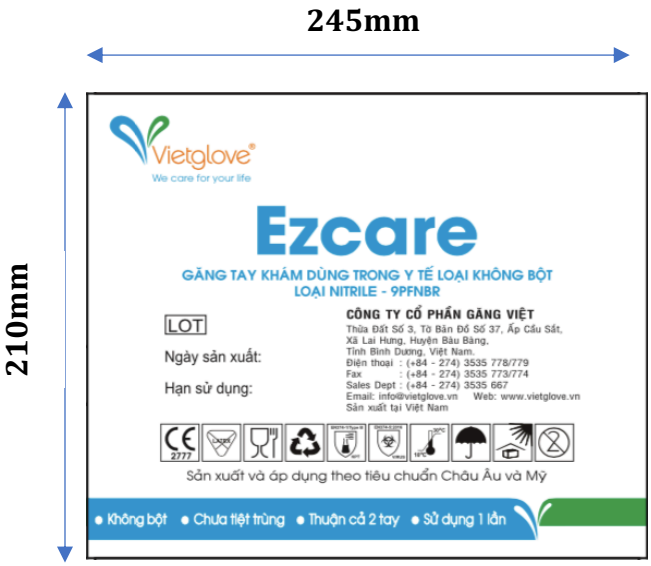
Hình ảnh hộp/ Dispenser pictuer

Hình ảnh sản phẩm/ Glove picture

PICTURES OF PRODUCT
HÌNH ẢNH SẢN PHẨM

Hình Ảnh Thùng Sản Phẩm:





bsi.

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

VIET GLOVE CORPORATION
No. 37, Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
75000
Vietnam

Holds Certificate Number: **FM 644239**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture and distribution of:
Non-sterile, powder free nitrile examination gloves
Non-sterile powder, powder free natural latex examination gloves (only labelling and packaging).

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2016-01-27
Effective Date: 2019-01-27
Latest Revision Date: 2019-01-25
Expiry Date: 2022-01-26

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

VIET GLOVE CORPORATION
No. 37, Cau Sat, Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
75000
Vietnam

Holds Certificate Number: **MD 644242**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The manufacture and distribution of:
Non - sterile powder, powder free nitrile examination gloves;
Non - sterile powder, powder free natural latex examination gloves (only labelling and packaging).

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-01-26
Effective Date: 2019-01-26
Latest Revision Date: 2019-01-11
Expiry Date: 2022-01-25

UKAS MANAGEMENT SYSTEMS 003

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Certificate of Registration

SOCIAL ACCOUNTABILITY SYSTEM - SA 8000:2014

This is to certify that:

VIET GLOVE CORPORATION
No. 37, Cau Sat, Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate No: **SA 652311**

and operates a Social Accountability System which complies with the requirements of the Social Accountability Standard SA 8000:2014 for the following scope:

Please see scope page.

For and on behalf of BSI:

Managing Director, BSI India, Venkataram Arabolu

Original Registration Date: 2018-11-20
Effective Date: 2018-11-20
Latest Revision Date: 2018-11-20
Expiry Date: 2021-11-19

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BSI, The MIRA Corporate Suites (A-2), Plot 1 and 2, Ishwar Nagar, Mathura Road, New Delhi 110 065.
A Member of the BSI Group of Companies.

Certificate No: **SA 652311**

Registered Scope:

The manufacture and distribution of:
1.The manufacture and distribution of Non - sterile powder and powder free nitrile examination gloves through the process of Receipt of Nitrile Additive , Inspection , Storage, Compounding , Inspection ,Clean former, Coagulant, Coagulant Oven, Nitrile dipping, Re-vulcanize, Pre-Leaching tank, beading, Vulcanize , Post - Leaching (powder glove)/ cooling tank (free powder) , slurry tank (powder glove)/ chlorine dipping (free powder/Nitrile)/, Post - leaching (powder free/ Nitrile), last oven (drying), tripping, tumbling (latex), inspection, storage, packing, storage and delivery.
2. Labelling and packaging of Non-Sterile powder and powder free natural latex examination gloves through the process of Receipt of materials, Sorting, Packing and Finishing.

Outsourced Processes: Latex Gloves manufacturing
Contracted Processes: Nil.

Original Registration Date: 2018-11-20
Effective Date: 2018-11-20
Latest Revision Date: 2018-11-20
Expiry Date: 2021-11-19

BSI, The MIRA Corporate Suites (A-2), Plot 1 and 2, Ishwar Nagar, Mathura Road, New Delhi 110 065.
A Member of the BSI Group of Companies.

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Certificate of Registration

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that:

VIET GLOVE CORPORATION
No.37, Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **BSIVN 1297/2019**

and operates a Good Manufacturing Pratice which complies with the requirements of GMP (CAC/RCP 1-1969, Rev.4-2003) the following scope:

The manufacture and distribution of:
Non-sterile, powder free nitrile examination gloves.
Non-sterile powder, powder free natural latex examination gloves (only labelling and packaging).

For and on behalf of BSI: Le Duyen Anh, Managing Director Vietnam

Original Registration Date: **19/02/2019**
Effective Date: **19/02/2019**
Latest Revision Date: **19/02/2019**
Expiry Date: **18/02/2022**

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Giấy Chứng Nhận

THỰC HÀNH SẢN XUẤT TỐT – GMP

Xác nhận rằng: **CÔNG TY CỔ PHẦN GĂNG VIỆT**
Số 37, Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **BSIVN 1297/2019**

và thực hiện Thực Hành Sản Xuất Tốt phù hợp với các yêu cầu của GMP (CAC/RCP 1-1969, Rev.4-2003) cho phạm vi:

Sản xuất và phân phối:
Găng tay y tế nitrile không tiệt trùng, không bột.
Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột (chỉ dán nhãn và đóng gói).

Đại diện cho tập đoàn BSI: *Tổng Giám đốc BSI Việt Nam, Ông Lê Duyên Anh*

Ngày đăng ký đầu tiên: **19/02/2019**
Ngày sửa đổi sau cùng: **19/02/2019**

Ngày hiệu lực: **19/02/2019**
Ngày hết hiệu lực: **18/02/2022**

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Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM – BSI HACCP & GMP

This is to certify that:

VIET GLOVE CORPORATION
No.37, Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **HACCP 730307**

and operates a food safety management system that complies with the requirements of Codex Alimentarius Alinorm: 2003/13A (HACCP) and Good Manufacturing Practice (GMP) for the accompanying scope:

The manufacture of:
Non-sterile, powder free nitrile examination gloves for food industry;
Non-sterile powder, powder free natural latex examination gloves (only labelling and packaging) for food industry.

For and on behalf of BSI: Le Duyen Anh, Managing Director Vietnam

Original Registration Date: **29/05/2020**
Latest Revision Date: **29/05/2020**

Effective Date: **29/05/2020**
Expiry Date: **28/05/2023**

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BSI Vietnam Headquarters: Suite 1106, 11th Floor, Citilight Tower, 45 Vo Thi Sau Street, Dakao Ward, District 1, HCMC, Vietnam. Telephone: +84 (28) 3820 0066.
A member of the BSI Group of Companies.

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By Royal Charter

Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ AN TOÀN THỰC PHẨM – BSI HACCP & GMP

Xác nhận rằng:

CÔNG TY CỔ PHẦN GĂNG VIỆT
Số 37, Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **HACCP 730307**

và vận hành hệ thống quản lý An Toàn Thực Phẩm tuân thủ các yêu cầu của Codex Alimentarius Alinorm: 2003/ 13A (HACCP) và Thực Hành Sản Xuất Tốt (GMP) cho phạm vi:

Sản xuất:
Găng tay y tế nitrile không tiệt trùng, không bột cho ngành công nghiệp thực phẩm.
Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột (chỉ dán nhãn và đóng gói) cho ngành công nghiệp thực phẩm.

bsi. Certified

Đại diện cho tập đoàn BSI: *Tổng Giám đốc BSI Việt Nam, Ông Lê Duyên Anh*

Ngày đăng ký đầu tiên: **29/05/2020**
Ngày sửa đổi sau cùng: **29/05/2020**

Ngày hiệu lực: **29/05/2020**
Ngày hết hiệu lực: **28/05/2023**

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Certificate of CE-Registration

mdi Europa

This is to certify that, in accordance with either medical device Directive 93/42/EEC as amended by 2007/47/EC or Directive 98/79/EC, mdi Europa GmbH agree to perform all duties and responsibilities as the Authorized Representative for

Hiermit wird bestätigt, daß mdi Europa GmbH als Bevollmächtigter gemäß § 7 Medizinproduktegesetz (MPG/nationale Umsetzung der Richtlinie für Medizinprodukte 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG) für den Hersteller

Viet Glove Corporation
Plot 03, Map No. 37
Cau Sat Hamlet, Lai Hung Village
Bau Bang District, Binh Duong Province
Vietnam

as stipulated and demanded by the afore-mentioned Directives. The German competent authorities have allocated the medical devices of the manufacturer the following registration numbers:

die Anzeigepflicht gemäß § 25 MPG für die nachfolgend aufgeführten Medizinprodukte erfüllt hat. Den angezeigten Medizinprodukten sind die folgenden Registrierdaten zugeordnet worden:

Medical Device	UMDNS Code	Registration-No.
Powder Free Nitrile Examination Glove Powder Free Latex Examination Glove Powder Latex Examination Glove	11882 –Class I	DE/CA09/0760/1900

The manufacturer has provided mdi Europa with all necessary documentation, together with an appropriate Declaration of Conformity confirming that the medical devices fulfill the essential requirements of either Directive 93/42/EEC as amended by 2007/47/EC or 98/79/EC. A safety officer has been appointed for Germany and therefore is in full compliance with § 31 MPG.

Der Hersteller hat mdi Europa alle für das erstmalige Inverkehrbringen von Medizinprodukten erforderlichen Dokumente vorgelegt. Dazu gehört die Konformitätserklärung, die bestätigt, daß die Produkte die grundlegenden Anforderungen der Richtlinie 93/42/EWG gem. Änderungsrichtlinie 2007/47/EG bzw. 98/79/EG erfüllen. Ein Sicherheitsbeauftragter gemäß § 31 MPG wurde bestellt.

June 2016

Werner Sander
President & CEO

Test Report No. 7191213380-EEC19-WBH
dated 10 Jul 2019

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 Power-free Gloves submitted by VIET GLOVE CORPORATION on 20 Jun 2019.

TESTED FOR:

VIET GLOVE CORPORATION
Plot 03, Map No.37, Cau Sat Hamlet,
Lai Hung Village, Bau Bang District,
Binh Duong Province,
Vietnam 590000.

TEST DATE:

20 Jun 2019 to 10 Jul 2019

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Powder Free Nitrile Gloves	Blue	- (see Remark 1)	M	400	Viet Glove Corporation

Lot size as specified by client: 150,001 to 500,000 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
   - Clause 4 Dimensions
   - Clause 5 Strength

3. EN 455-3:2015 Medical glove for single use
   Part 3: Requirements and testing for biological evaluation
   - Clause 4.4 Powder-free gloves

TÜV SÜD PSB

Laboratory:
TÜV SÜD PSB Pte. Ltd.
No.1 Science Park Drive
Singapore 118221

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

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

PSB Singapore

RESULTS:

Sample: Powder Free Nitrile Gloves, Size M

Table 1: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	315	7	Passed

Table 2: Results for EN 455-2:2015 Clauses 4-5

Clause	Tests	Requirements (Median)	Number tested (pieces)	Results (Median)	Inferred results
4	Dimensions a) Length (mm)	Median Length for size M: ≥ 240	13	247	Passed
	b) Width (mm)	Median Width for size M: 95 ± 10	13	96	Passed
5	Strength a) Force at break (N)	For examination gloves: ≥ 6.0	13	6.1	Passed
	b) Force at break after challenge testing (N) 7 days at (70 ± 2)°C	For examination gloves: ≥ 6.0	13	6.4	Passed

Table 3: Results for EN 455-3:2015 Clause 4.4

Clause	Tests	Requirements	Results	Inferred results
4.4 5.2	Powder-free gloves	For powder-free gloves: The total quantity of powder residues shall not exceed 2 mg per glove.	0.23 mg per glove	Passed

REMARKS:

1) The manufacturing batch code was not provided by the client.

Lee Dai Yi
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo: Powder Free Nitrile Gloves, Size M

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

Authorized Representation Agreement

For Medical Device CE-Marking

Preamble/Introduction.

THE COUNCIL OF THE EUROPEAN COMMUNITIES, having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof, legally ratified and published the following Council Directives, aimed at regulating the manufacture of medical devices and the freedom of movement of medical devices within the European Communities:

COUNCIL DIRECTIVE 90/385/EEC (and revision 2007/47/EEC)
- of 20 June 1990 – active implantable medical devices
COUNCIL DIRECTIVE 93/42/EEC (and revision 2007/47/EEC)
- of 14 June 1993 - medical devices
COUNCIL DIRECTIVE 98/79/EEC
- of 27 October 1998 - in vitro diagnostic medical devices

Medical devices must bear the CE Marking of conformity when they are placed on the market and the CE Marking must appear in a visible, legible and indelible form on the device or its sterile pack and where appropriate and practicable, on the instructions for use.

THIS AUTHORIZED REPRESENTATION AGREEMENT (Agreement) is entered into on this day

1st January 2016

BY AND BETWEEN:

"The Manufacturer"
VIET GLOVE CORPORATION
Cau Sat Hamlet, Lai Hung Commune,
Bau Bang District, Binh Duong Province,
Vietnam

AND:

"The Authorized Representative"
Mdi Europa GmbH
Langenhagener Str. 71
D-30855 Langenhagen

WHEREAS, a non-European medical device manufacturer WITHOUT either manufacturing location or facility in a member state of the European Community or a subsidiary in a member state of the European Community is legally obliged to appoint a European person, or persons or regulatory affairs company (hereafter authorized representative) with a business location within a member state of the European Community

WHEREAS, the appointment of an authorized representative of a non-European medical device manufacturer is an essential requirement within the context defined within the Directives

WHEREAS, "authorized representative" means: *any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under the Directive;*

WHEREAS, the medical device manufacturer desires to ensure that all product(s) distributed and supplied by the manufacturer carry the CE Marking of conformity and are therefore in full compliance to ONE of the above-mentioned European Council Directives regulating the manufacture and free movement of medical devices within the European Community

NOW, THEREFORE, both parties agree in consideration of the mutual commitments and promises contained herein, to the following:

§ 1
Authorized Representative
(Hereafter AR)

1.
In accordance with the "essential requirements" of the Directive(s), the AR permits the manufacturer to use the registered name/trade name "mdi Europa GmbH" together with the full postal address for the sole purpose of inclusion/printing on all packaging, labeling and instructions for use that carry CE Marking and that have been appropriately registered by the AR with the European competent authorities.

2.
The AR will notify the German competent authorities of this Agreement and register not only themselves but also the manufacturer, and the devices of the manufacturer in an appropriate and timely manner as required and stipulated by the most current European requirements. These requirements are laid down in the various Guidelines (MEDDEV documents) pertaining directly to the Directives themselves.

3.
The AR will appoint (for Germany) a "safety officer" to act for and on behalf of the manufacturer in accordance with Federal German laws and legislations. The German law (MPG) regulating medical devices is the direct transposition of the Directives into German national legislation. (The member state governing the AR).

4.
The AR acknowledges and accepts full responsibility for reporting all (possible) incidents and near incidents with the appropriate and pertinent European competent authority, depending upon the location of the (possible) incident or near incident. The AR will attempt to gain as much information as possible from distributors and/or end users in conjunction with the (supposed) incident or near incident and place this information at the disposal of the manufacturer.
(Possible) incidents/near incidents MUST be reported in the timeframes stipulated and laid down by the most current Vigilance Guidelines (MEDDEV) on Incident Reporting within the European Community i.e. 10 days and 30 days respectively. Where appropriate, the format for reporting will be that of DIMDI, the organization charged by the European Community with the responsibility for maintaining the European databank for incidents / near incident reporting (and CE Marking registration).

5.
The AR will attempt to access from end users and/or distributors any device(s) that have been the cause of a (possible) incident/near incident and forward theses devices on to the manufacturer by the fastest and safest possible means, (taking into account the likelihood of contamination when selecting the appropriate method of shipment)!

6.
Only upon explicit and prior request from the manufacturer, the AR will seek the opinion of a medical device expert or a suitable physician for consultation purposes regarding any incidents/near incidents. Upon explicit and prior request from the manufacturer, the AR commit to help and assist the manufacturer in obtaining competent European legal advice and assistance in any member state where an incident/near incident has indeed occurred and where resulting legal help and assistance is possibly helpful or necessary.

Also upon explicit request, the AR will apply for Free Sales Certificates on behalf of the manufacturer. The cost for a FSC including one product group are EUR 380,00 plus EUR 50,00 per additional product group. Additional cost for legalization (if necessary) have to be calculated in addition per the charges defined by the applicable embassy
NOTE: additional costs/fees for expert help, legal advice etc. are the sole responsibility of the manufacturer and are NOT included in the annual fee structure defined within this Agreement.
(See Fee Structure / Remuneration).

7.
The AR commit to doing everything possible to observe and monitor all changes in European legislation governing medical devices, the Directives and guidance documents and to act in accordance with those changes in both requirements and law. Where appropriate, the AR will report these changes to the manufacturer and keep the manufacturer informed and updated accordingly.

8.
The AR is obliged to report directly to:
Terence Lim, Quality & Regulatory Affairs Consultant

All correspondence is to be directed to the above designated person, (unless following signature and exchange of this Agreement, the AR receives instructions from the manufacturer to the contrary).

9.
The AR has full responsibility towards the Officers and Staff of mdi Europa GmbH and will meet any and all the claims of its employees. The AR is considered to be an independent agent / vendor of the manufacturer and must act accordingly.

Independent and regardless of the fact that the AR is located and based in Germany, the common language of communication and correspondence between the AR and the manufacturer will be in either UK English or US English only.

§ 2
The Manufacturer
1.
The manufacturer will immediately provide the AR with all necessary documentation and information pertaining to those medical devices that are to be registered by the AR for CE Marking within the Community. Documentation must include the full technical files for all products being registered, together with supportive Declarations of Conformity and where appropriate, certification issued by a European notified body. Additional information may be required but only to the degree that this information is indeed available and is in the possession of the manufacturer.

2.
The manufacturer understands that **the technical files being held by the AR and will be treated at all times with the utmost confidentiality**. The technical files & documentation are, however, subject to the scrutiny and audit (for CE Marking compliance) by any European competent authority, without just reason or cause and at any given time. The manufacturer agrees to allow ONLY a competent authority/governmental body access to these otherwise confidential files and supportive documents.

3.
The manufacturer will immediately inform the AR of any fundamental or significant changes to either the design or basic functionality or safety of those medical devices that have been registered for CE Marking. The manufacturer will immediately supply the AR with the necessary supportive documentation reflecting these changes in accordance with § 2.1 of this Agreement.

4.
Should the AR recommend immediate action / corrective action be taken by the manufacturer to avoid either minor and/or major breaches in European legislation (and member state national laws), and should the manufacturer deem or consider it necessary or appropriate NOT to follow such recommendations, then the AR has the right to take only appropriate action to protect both itself and its employees. Protective action of this nature by the AR does not require prior, express written or verbal permission from the manufacture. Protective actions for and on behalf of the AR will be at the sole responsibility of the AR and the AR will carry all resulting cost(s) and expenses.

§ 3
Limitation of Liability

The AR shall not be liable for any damage sustained by the AR due to or in connection with or in consequence of the performance or non-performance of services under this Agreement unless caused by wilful misconduct or gross negligence of the AR or in the event that the AR guaranteed a specific quality or the AR maliciously withholds a defect.

§ 4
Product Liability Insurance Coverage

1.
It must be assumed that the AR *could be held liable for third party liability and damage claims* due to the fact that the AR's name and address has been included either on the packaging and/or labeling and/or instructions for use! The manufacturer will therefore immediately include the AR within the scope of the manufacturers Product Liability Insurance Coverage (minimum two million US-Dollars) and, where appropriate, issue the AR with a "Certificate of ACORD" or other appropriate form/evidence of product liability insurance, explicitly naming the AR as certificate /policy holder.

2.
Product Liability Insurance Coverage will be maintained and upheld by the manufacturer throughout the duration of this contract and following thereafter for a minimum period of five (5) years, or for as long as those medical devices carrying the AR's name and address are either in circulation, have been put into service or remain in the market of the European Community, (whichever being the longest period of time).

3.
Medical device manufacturers WITHOUT appropriate Product Liability Insurance Coverage will hold the AR free and harmless at all times against any and all liability claims for either bodily injury and/or property damage and/or other possible claims resulting from either the use, sale or delivery of medical devices and which have been directly manufactured by or indirectly manufactured for and on behalf of (OEM) the manufacturer.

4.
The manufacturer shall not insure the AR against liability claims incurred by the AR and which are the result(s) of either gross negligence, wilful misconduct, wrongful acts, unauthorized activities and/or behavior, omissions of legal duties and responsibilities by the AR towards the European Community and its' Directives, or any breach of this Agreement.

§ 5
Commencement /Duration of the Agreement

1.
The Agreement becomes immediately effective upon successful signature and mutual exchange of Agreements and on the date clearly reflected below the "Preamble/Introduction" which appears on the first page of this Agreement and shall continue and remain valid and binding for an indefinite period until terminated by either party at any time upon **three (3) months (90 days) advance written notice has been appropriately submitted by the terminating party.**

2.
The Agreement can be terminated at any time by either party should one of the parties breach this Agreement and following written notification of the breach by the offended party and of their resulting intention to invoke an early termination under this clause. The offending party has the right to cure the breach within fifteen (15) calendar days following written notification from the offended party, thus avoiding early termination of the Agreement under this particular clause.

3.
The AR reserves the right to terminate this Agreement without further notice or warning should the Product Liability Insurance Coverage required by the AR and which is covered under § 3.1 and § 3.2 of this Agreement not be renewed appropriately upon expiry, or become invalid or become null and void or be revoked for any reason whatsoever, unless the manufacturer replaces or reinstates the Product Liability Insurance Coverage within 10 days following said reason(s) or expiration.

4.
Following the timely termination of this Agreement, the manufacturer must remove all indication of the AR (including name and address) from further new production and from any and all packaging, labeling and instructions for use.

5.
Upon expiration / termination of this Agreement, the AR will promptly notify the competent authorities and inform them in the appropriate manner that mdi Europa GmbH is no longer the AR of the manufacturer. Any and all medical device registrations indicating or notifying the competent authorities of the fact that mdi Europa GmbH was the Authorized Representative must (!) and will also be revoked.

6.
Upon expiration / termination of this Agreement, the AR will immediately return all technical files, documentation and property etc. belonging to the manufacturer.

§ 6
Product Mix / Product Coverage
(Under this Agreement)

1.
The Agreement covers all medical devices and/or in vitro diagnostic medical devices listed and identified within Appendix 1 (EC Declaration of Conformity) of this Agreement. Both parties are aware that the manufacturer is permitted to delete, update, renew or extend the products listed within Appendix 1 (EC Declaration of Conformity) as necessary and appropriate and at any time throughout the duration of the Agreement. The manufacturer will submit to the AR a revised Appendix 1 (EC Declaration of Conformity) each and every time a product is either deleted and/or added. The AR will act solely each time upon Appendix 1 (EC Declaration of Conformity) and register / de-register the products listed and contained therein. The AR will issue the manufacturer with a "Certificate of CE-Registration" confirming and reflecting the current and thus most recent Appendix 1 (EC Declaration of Conformity).

mdi Europa

§ 7
Fee Structure / Remuneration

1.
The manufacturer agrees to pay the AR an **annual fee of**

Euro 1.300,00

throughout the duration of the Agreement. The annual payment is not only for the duties and responsibilities of the AR defined within this Agreement but also for the free use of the AR company name and address for the sole purpose of inclusion on packaging, labeling and instructions for use. (See § 1.1)

2.
At the end of every three year period from the date of signature and exchange of this contract, the parties will mutually agree on a fair equitable adjustment rate which shall apply to the annual fee under §7.1 of this contract. The adjustment rate shall not accede 15% of the annual rate under §7.1 of this contract.

3..
The AR commits to reporting any and all (possible) incidents/incidents, as and when they occur. **The fee structure is fixed for the duration as stipulated in § 7.2, regardless of the number of products the manufacturer wishes registered or de-registered and that have been/are defined within the most current and thus up-to-date Appendix 1 (EC Declaration of Conformity).**

§ 8
Confidentiality

Both parties will not disclose any details connected with this Agreement to any third party without first obtaining the written consent of the other party except as required by law or to enforce any provision of this Agreement.

§ 9
Place of Jurisdiction, Fulfillment & Domicile

Place of jurisdiction and fulfillment of the Agreement is the domicile of the AR and the Agreement is therefore subject to the laws and jurisdiction of the Federal Republic of Germany.

APPENDIX 1 – EC Declaration of Conformity

Appendix 1 is the standard EC Declaration of Conformity as issued by the manufacturer, listing those products/medical devices/in vitro diagnostic medical devices that the manufacturer wishes to register for the purposes of CE-Marking under the Council Directive(s) of the European Communities. Appendix 1 is only valid when signed by the manufacturer and is understood by the manufacturer to be the Declaration (affidavit) AND SOLE RESPONSIBILITY of the manufacturer that the products /medical devices/in vitro diagnostic medical devices listed therein are indeed in full compliance with the appropriate Council Directive(s) aimed at regulating the products/medical devices/in vitro diagnostic medical devices of the manufacturer. The manufacturer is aware that a false or untrue Declaration of Conformity is a serious and grave offense under European Council and European Community legislation.

December 2015

Mdi Europa GmbH
Represented by
Werner Sander – President

Viet Glove Corporation
Represented by:
Pham Ngoc Thanh's – Managing Director

mdi Europa GmbH – Langenhagener Straße 71 – 30855 Langenhagen

Viet Glove Corporation
Cau Sat Hamlet
Lai Hung Commune,
Bau Bang District
Binh Duong Province

Vietnam

23 January 2019

Confirmation of renewal of our existing contract

This is to confirm that the existing contract between Viet Glove Corporation and mdi Europa GmbH is renewed without time limit.

Werner Sander
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 1, 2016

Viet Glove Corporation
Mr. Terence Lim
Quality Assurance & Regulatory Affairs Manager
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Bau Bang Province
VIETNAM

Re: K153562
Trade/Device Name: Powder Free Blue Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA
Dated: February 23, 2016
Received: March 4, 2016

Dear Mr. Terence Lim:

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. 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-

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K153562

Device Name
POWDER FREE BLUE NITRILE EXAMINATION GLOVE

Indications for Use *(Describe)*
A 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

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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."

20286

BỘ KHOA HỌC VÀ CÔNG NGHỆ
CỤC SỞ HỮU TRÍ TUỆ

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

GIẤY CHỨNG NHẬN
ĐĂNG KÝ NHÃN HIỆU
Số: 299487

Chủ Giấy chứng nhận: CÔNG TY CỔ PHẦN GĂNG VIỆT (VN)
Thửa đất số 03, tờ bản đồ số 37, ấp Cầu Sắt, xã Lai Hưng, huyện Bàu Bàng, tỉnh Bình Dương

Số đơn: 4-2015-35556

Ngày nộp đơn: 16/12/2015

Cấp theo **Quyết định số**: 31756/QĐ-SHTT, **ngày**: 10/05/2018

Có hiệu lực từ ngày cấp đến hết 10 năm tính từ ngày nộp đơn (có thể gia hạn).

C.H.X.H.C.N VIỆT NAM
CỤC SỞ HỮU TRÍ TUỆ
NATIONAL OFFICE OF INTELLECTUAL PROPERTY OF VIETNAM
BỘ KHOA HỌC VÀ CÔNG NGHỆ

CỤC TRƯỞNG

CỘNG HÒA X.H.C.N VIỆT NAM
CỤC SỞ HỮU TRÍ TUỆ
BỘ KHOA HỌC VÀ CÔNG NGHỆ

VN 4-0299487

Đinh Hữu Phí

GIẤY CHỨNG NHẬN ĐĂNG KÝ NHÃN HIỆU SỐ: 299487
Mẫu nhãn hiệu:

Mầu sắc nhãn hiệu: Da cam, xanh dương, xanh dương nhạt, xanh lá cây, trắng.

Loại nhãn hiệu: Thông thường

Nội dung khác: Nhãn hiệu được bảo hộ tổng thể. Không bảo hộ riêng "We care for your life".

Danh mục sản phẩm/ dịch vụ mang nhãn hiệu:

Nhóm 10: Găng tay dùng trong y tế.

CÔNG TY TNHH CÔNG NGHỆ ADJ VIỆT NAM	**CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM** **Độc lập - Tự do - Hạnh phúc**
Số: 20191573 -ADJVINA/ 170000008/PCBPL-BYT	*Hà Nội, ngày 23 tháng 12 năm 2019*

BẢN KẾT QUẢ PHÂN LOẠI TRANG THIẾT BỊ Y TẾ

Căn cứ Nghị định số 36/2016/NĐ-CP ngày 15 tháng 5 năm 2016 của Chính phủ nước Cộng hòa xã hội chủ nghĩa Việt Nam về Quản lý trang thiết bị y tế;

Căn cứ Nghị định 169/2018/NĐ-CP ngày 31 tháng 12 năm 2018 của Chính phủ sửa đổi, bổ sung một số điều của Nghị định số 36/2016/NĐ-CP ngày 15 tháng 5 năm 2016 của Chính phủ về Quản lý trang thiết bị y tế;

Căn cứ Phiếu tiếp nhận hồ sơ công bố đủ điều kiện phân loại số 170000008/PCBPL-BYT do Bộ Y tế cấp ngày 27/02/2017;

Căn cứ giấy chứng chỉ hành nghề phân loại của người thực hiện phân loại số: 19000522/ BYT-CCHNPL, ngày cấp: 13/08/2019;

Theo yêu cầu của **CÔNG TY CỔ PHẦN GĂNG VIỆT**, có địa chỉ tại: Thửa đất số 03, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương, Việt Nam, chúng tôi phân loại trang thiết bị y tế như sau:

Theo phụ lục đính kèm

Người thực hiện phân loại	**CÔNG TY TNHH CÔNG NGHỆ ADJ VIỆT NAM**
Trần Nhật Quân	GIÁM ĐỐC *Dương Thùy Linh*
Trang thiết bị y tế không là trang thiết bị y tế chẩn đoán in vitro	

Nơi nhận:
- Bộ Y tế;
- Sở Y tế các tỉnh, thành phố;
- Hải quan cửa khẩu;
- Lưu: VT.

PHỤ LỤC ĐÍNH KÈM

Kèm theo Bản kết quả phân loại trang thiết bị y tế số: 20191573 -ADJVINA/170000008/PCBPL-BYT

TT	Tên trang thiết bị y tế	Chủng loại/ mã sản phẩm	Hãng, nước sản xuất	Hãng, nước chủ sở hữu	Mục đích sử dụng theo chỉ định của chủ sở hữu	Căn cứ để phân loại mức độ rủi ro	Mức độ rủi ro được phân loại
1.	Găng tay y tế	9PFNBR	Công ty Cổ Phần Găng Việt, Việt Nam	Công ty Cổ Phần Găng Việt, Việt Nam	Găng tay khám dùng trong y tế loại không bột (loại Nitrile) dùng để thăm khám cho bệnh nhân	Quy tắc 5, Mục B, Phần II, phụ lục I Thông tư 39/2016/TT-BYT	A
2	Găng tay y tế	9PFNR	Công ty Cổ Phần Găng Việt, Việt Nam	Công ty Cổ Phần Găng Việt, Việt Nam	Găng tay khám dùng trong y tế loại không bột (loại cao su thiên nhiên) dùng để thăm khám cho bệnh nhân	Quy tắc 5, Mục B, Phần II, phụ lục I Thông tư 39/2016/TT-BYT	A
3	Găng tay y tế	9PDNR	Công ty Cổ Phần Găng Việt, Việt Nam	Công ty Cổ Phần Găng Việt, Việt Nam	Găng tay khám dùng trong y tế loại có bột (loại cao su thiên nhiên) dùng để thăm khám cho bệnh nhân	Quy tắc 5, Mục B, Phần II, phụ lục I Thông tư 39/2016/TT-BYT	A

Trong quá trình lưu hành sản phẩm đơn vị có trách nhiệm:
In the product's circulation and business activities, it is required to strictly obey the following obligations:

1. Chấp hành đầy đủ các quy định về quản lý trang thiết bị y tế của Việt Nam.
Comply with the Vietnam regulations on management of medical devices.

2. Chịu trách nhiệm về chất lượng sản phẩm đã đăng ký và hoạt động sản xuất kinh doanh trên thị trường theo quy định của pháp luật Việt Nam.
Have full responsibility on quality of the product registeredand Company's operations on the market in accordance with the Vietnam laws.

3. Thông báo cho Bộ Y tế trước 30 ngày trong các trường hợp sau:
Inform to the Ministry of Health 30 days in advance in the following cases:
- Thay đổi tên, địa chỉ *(change in the name or address of the Company)*
-Mọi sự thay đổi liên quan đến sản phẩm *(Any change of the registered product)*
- Tách, sáp nhập, đổi tên hoặc chấm dứt hoạt động sản xuất kinh doanh *(Separation, merger or termination of the Company's operations)*

4. Giấy chứng nhận này có giá trị 03 (ba) năm kể từ ngày ký. Trước khi hết hạn 30 (ba mươi) ngày, đơn vị phải làm thủ tục xin gia hạn đăng ký nếu vẫn tiếp tục lưu hành sản phẩm trên.
This certification is valid for three (03) years from the date of signing. Before its expiration date of thirty (30) days, it is required to renew the validity of certification if the product is continuing circulation in Vietnam.

TL. BỘ TRƯỞNG
VỤ TRƯỞNG
VỤ TRANG THIẾT BỊ VÀ CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL DEVICES & CONSTRUCTION
DIRECTOR

Nguyễn Minh Tuấn

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM
SOCIALIST REPUBLIC OF VIETNAM

BỘ Y TẾ
MINISTRY OF HEALTH

GIẤY CHỨNG NHẬN

ĐĂNG KÝ LƯU HÀNH SẢN PHẨM TRANG THIẾT BỊ Y TẾ TẠI VIỆT NAM

CERTIFICATE

REGISTRATION FOR CIRCULATION OF
MEDICAL DEVICES MANUFACTURING IN VIETNAM

BỘ Y TẾ
Số (No): 69 /2016/BYT-TB-CT

Hà Nội, ngày (date): 23 / 9 /2016

GIẤY CHỨNG NHẬN
ĐĂNG KÝ LƯU HÀNH SẢN PHẨM TRANG THIẾT BỊ Y TẾ SẢN XUẤT TẠI VIỆT NAM

CERTIFICATE
REGISTRATION FOR CIRCULATION OF
MEDICAL DEVICES MANUFACTURING IN VIETNAM

- Căn cứ Nghị định số 63/2012/NĐ-CP ngày 31 tháng 8 năm 2012 của Chính phủ quy định chức năng, nhiệm vụ, quyền hạn và cơ cấu tổ chức của Bộ Y tế;
Pursuant to Decree No. 63/2012/NĐ-CP dated August 31st, 2012 issued by Government stipulating the functions, tasks, authority and organizational structure of the Ministry of Health;
- Căn cứ Luật Chất lượng sản phẩm, hàng hoá ngày 21 tháng 11 năm 2007;
Pursuant to Law on Quality of products and goods dated November 21st, 2007;

- Căn cứ Thông tư số 07/2002/TT-BYT ngày 30 tháng 5 năm 2002 của Bộ Y tế về hướng dẫn đăng ký lưu hành sản phẩm trang thiết bị y tế.
Pursuant to Circular No. 07/2002/TT-BYT dated May 30, 2002 of the Ministry of Health on guiding for circulation registration of medical devices.

- Xét hồ sơ và đơn đề nghị cấp số đăng ký lưu hành sản phẩm của đơn vị.
Having examination of documentation and application letter for circulation of medical device submitted by the applicant.

BỘ Y TẾ CHỨNG NHẬN
MINISTRY OF HEALTH CERTIFIES THAT

Nhà sản xuất (Manufacturer): CÔNG TY CỔ PHẦN GĂNG VIỆT

Địa chỉ (Address): Thửa Đất Số 3, Tờ Bản Đồ Số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương,Việt Nam

Địa chỉ sản xuất (Site Address): Thửa Đất Số 3, Tờ Bản Đồ Số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương,Việt Nam

ĐƯỢC PHÉP LƯU HÀNH TẠI VIỆT NAM SẢN PHẨM
HAS A PERMISSION TO CIRCULATE THE FOLLOWING MEDICAL DEVICES IN VIETNAM

Tên sản phẩm Name of Product(s)	**Mã hiệu sản phẩm** Model	**Tiêu chuẩn công bố** Declared standard
1. Găng Tay Y Tế Không Bột Nitrile (Loại Nitrile)	9PFNBR	ASTM D 6319
2. Găng Tay Cao Su Y Tế Không Bột (loại cao su thiên nhiên)	9PFNR	ASTM D 3578-05
3. Găng Tay Cao Su Y Tế Có Bột (loại cao su thiên nhiên)	9PDNR	ASTM D 3578-05
4. Găng Tay Phẫu Thuật Tiệt Trùng và Chưa Tiệt Trùng (loại cao su thiên nhiên)	9SURG	TCVN 6344:2007

Số đăng ký lưu hành được cấp: 69...../2016/BYT-TB-CT
(Registered number)

BỘ Y TẾ VIỆT NAM
VIET NAM MINISTRY OF HEALTH

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc
SOCIALIST REPUBLIC OF VIETNAM
Independence-Freedom-Happiness

GIẤY CHỨNG NHẬN LƯU HÀNH TỰ DO
CERTIFICATE OF FREE SALES

Giấy chứng nhận số: 56 **/2018/BYT-TB-CT**
Certificate No:

STT	Tên Sản phẩm Name of Product(s)	Chủng loại/Model
1	Găng tay khám dùng trong y tế loại không bột (loại Nitrile) Powder Free Nitrile Examination Glove	9PFNBR
2	Găng tay khám dùng trong y tế loại không bột (Loại cao su thiên nhiên) Powder Free Latex Examination Glove	9PFNR
3	Găng tay khám dùng trong y tế loại có bột (Loại cao su thiên nhiên) Powder Latex Examination Glove	9PDNR

Tên công ty sản xuất: Công ty Cổ phần Găng Việt
Manufacturer: VIET GLOVE CORPORATIONE

Địa chỉ: Thửa đất số 03, tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, tỉnh Bình Dương, Việt Nam.

Address: Land Lot No.03, Map No. 37, Cau Sat Hamlet , Lai Hung Commune, Bau Bang District, Binh Duong Province, Vietnam.

Văn bản này là để xác nhận rằng các sản phẩm trên tuân theo các tiêu chuẩn liên quan của Việt Nam hoặc tương đương và được phép bán tại Việt Nam. Việc xuất khẩu sản phẩm không bị hạn chế.

This is to certify that the above product(s) comply with the relevant standards of the S.R. Vietnam or equivalent and are allowed to be sold in Vietnam. The exportation of the product(s) is not restricted.

TL. BỘ TRƯỞNG
VỤ TRƯỞNG
VỤ TRANG THIẾT BỊ VÀ CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL DEVICE & CONSTRUCTION
DIRECTOR

Nguyễn Minh Tuấn

Chứng nhận này có hiệu lực từ 18 /12/**2018** **đến (to)** 18 /12/**2020**
This Certificate is valid from