Contact information:
VIET GLOVE CORPORATION
Email: thugiang@vietglove.vn
Hotline: +84 981 825 007
Website: http://vietglove.vn

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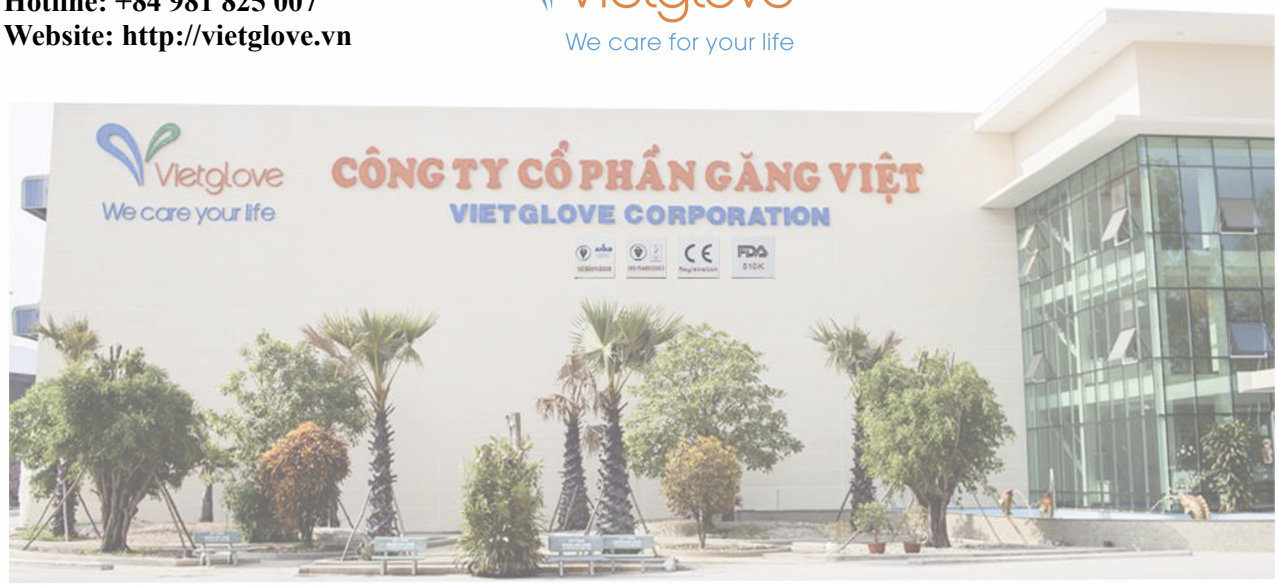
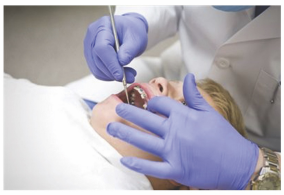


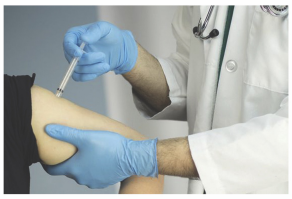
LEADING GLOVE MANUFACTURER IN VIETNAM

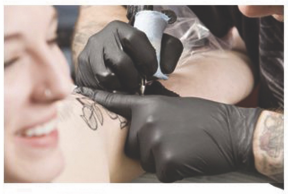
VIETGLOVE CORPORATION

NITRILE/LATEX EXAMINATION GLOVE

Non-Sterile | Ambidextrous | Powdered | Powder Free







ISO 13485:2016 Medical Device Quality Management

ISO 9001:2015 Quality Management

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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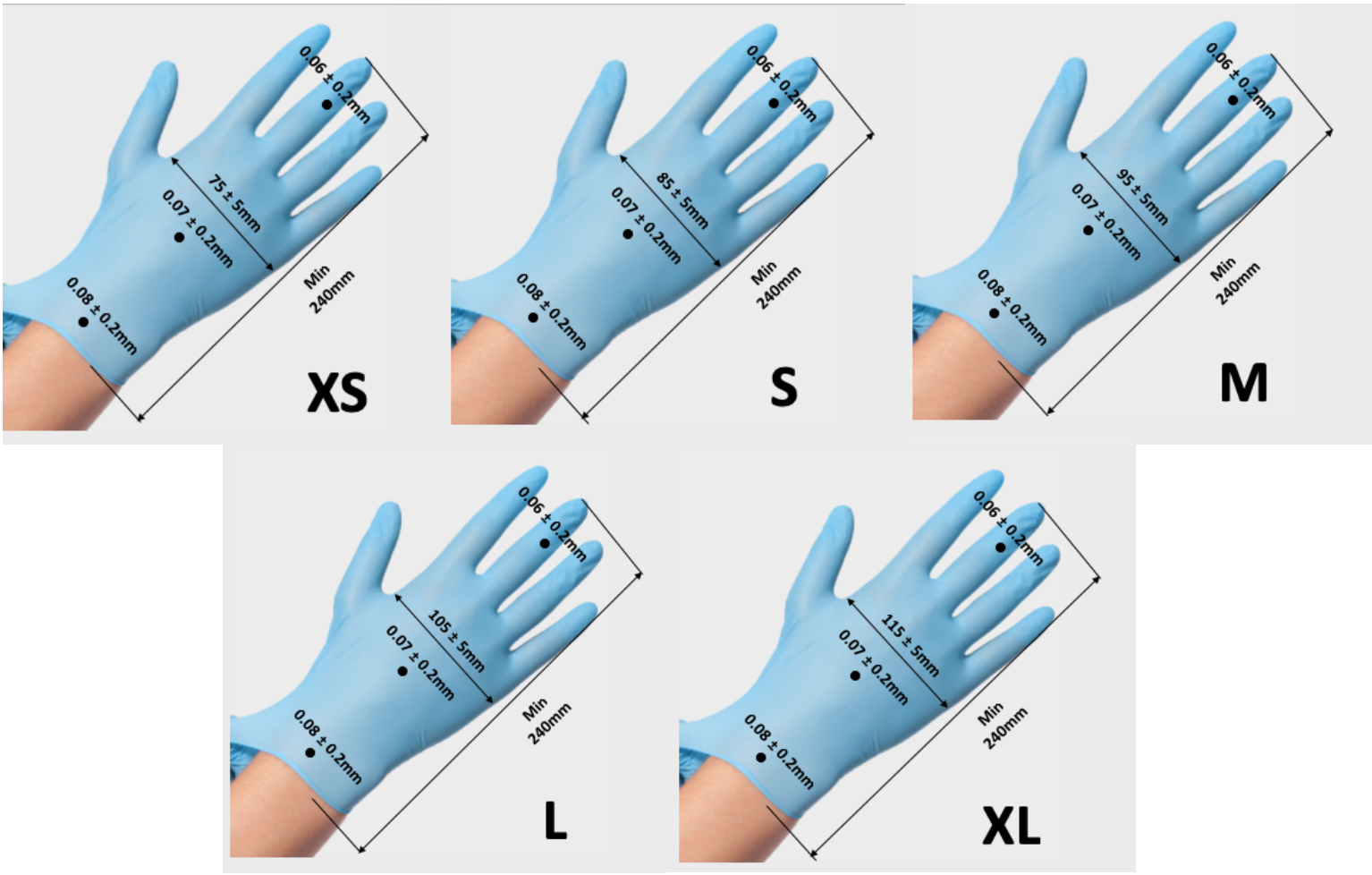
RANGE OF PRODUCT
LOẠI HÌNH SẢN PHẨM

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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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

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,
590000
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 free, powdered natural rubber latex examination gloves (only labelling and packaging).

For and on behalf of BSI:

Michael Lam - Managing Director Assurance, APAC

Original Registration Date: 2016-01-27
Effective Date: 2022-01-27
Latest Revision Date: 2021-12-16
Expiry Date: 2025-01-26

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By Royal Charter

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 Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
590000
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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-01-26
Effective Date: 2022-01-26
Latest Revision Date: 2021-12-30
Expiry Date: 2025-01-25

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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 Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province, 590000
Vietnam

Holds Certificate Number: **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:

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 process: Nil

Previous certificate expires on 19/11/2021
Recertification audit ended 23/06/2021

For and on behalf of BSI: Theuns Kotze, Managing Director - IMETA Assurance

Original Registration Date: **20/11/2018**
Effective Date: **24/01/2022**
Latest Revision Date: **24/04/2022**
Expiry Date: **19/11/2024**

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Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2018

This is to certify that:

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

Holds Certificate Number: **FSMS 737570**

and operates a Food Safety Management System which complies with the requirements of ISO 22000:2018 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).

Category: I

For and on behalf of BSI: Chris Cheung, Head of Compliance & Risk – Asia Pacific

Original Registration Date: **29/04/2021**
Latest Revision Date: **29/04/2021**

Effective Date: **29/09/2021**
Expiry Date: **28/04/2024**

ANAB
ANSI National Accreditation Board
ACCREDITED
ISO/IEC 17021-1
MANAGEMENT SYSTEMS
CERTIFICATION BODY

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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 trong ngành Công Nghệ Thực Phẩm; Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột (chỉ dán nhãn và đóng gói) trong ngành Công Nghệ Thực Phẩm.

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

Ngày đăng ký đầu tiên: **16/12/2021**
Ngày sửa đổi sau cùng: **16/12/2021**

Ngày hiệu lực: **16/12/2021**
Ngày hết hiệu lực: **15/12/2024**

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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: **16/12/2021**
Effective Date: **16/12/2021**
Latest Revision Date: **16/12/2021**
Expiry Date: **15/12/2024**

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VIET GLOVE CORPORATION
Land Lot No. 03 - Map No. 37 - Cau Sat Hamlet - Lai Hung Commune - Bau Bang District – Binh Duong Province – Vietnam
Tel: +84 274 3535 778/779 Fax: +84 274 3535 773/774
Email: info@vietglove.vn Website: www.vietglove.vn

EU DECLARATION OF CONFORMITY (EU DOC)

Manufacturing Site	: **VIET GLOVE CORPORATION**
	: Land Lot No. 03, Map No. 37, Cau Sat Hamlet,
	Lai Hung Commune, Bau Bang District,
	Binh Duong Province, Vietnam.
Single Registration Number (SRN)	: VN-MF-000009423
European Authorizied Representative	: **MDI Europa GmbH** Langenhagener Str. 71, D-30855 Langenhagen, Germany. Tel.: +49-511-3908 9530
Single Registration Number (SRN)	: DE-AR-000006218
Basic UDI-DI	: 8938508639VietNitrileTA
GMDN code and term	: 56286 Nitrile examination/treatment glove,
	non-powdered, non-antimicrobial
EMDN/CND	: T01020204 Examination/Treatment Gloves, Nitrile
Name of Device	: **Nitirle Examination Gloves**
Type	: Powder Free
Intended Purpose	: A patient examination glove is a disposable device
	Intended for medical purposes that is worn on the
	Examiners hand or finger to prevent contamination
	Between patient and examiner. Examination glove is
	Intended for medical activities except surgery.
Classification	: Class I, Non Sterile
Brand Name	: EZCARE
Size	: XS, S, M, L, XL
Conformity Assessment Procedure	: Annex I, Annex II and Annex IV (Self declared)
Rule	: Rule 5

VIET GLOVE CORPORATION
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Tel: +84 274 3535 778/779 Fax: +84 274 3535 773/774
Email: info@vietglove.vn Website: www.vietglove.vn

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documentations are retained under the premise of manufacturer.

This Declaration of Conformity is also issued on the basis of fulfilment the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III (Module C2):

- The conformity to type based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd.

Applicable Standards:

No	Standard	Descriptions	Date Published
1	EN 455-1:2020	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	May-2020
2	EN 455-2:2015	Medical gloves for single use - Part 2: Requirements and testing for physical properties	July 2015
3	EN 455-3:2015	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	July 2015
4	EN 455-4:2009	Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	October 2009
5	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices	December 2019
6	ISO 2859-1:1999	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	November 1999
7	ISO 10993-1:2018	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Aug 2018
8	ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	June 2009
9	ISO 10993-10:2021	Biological evaluation of medical devices Part 10: Tests for skin sensitization	November 2021
10	ISO 10993-11:2017	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	September 2017
11	ISO 10993-12:2021	Biological evaluation of medical devices Part 12: Sample preparation and reference materials	January 2021
12	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements	July 2021
13	MDR 2017/745 (Annex I: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
14	MDR 2017/745 (Chapter I: Article 2)	Scope and Definitions	April 2017

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Tel: +84 274 3535 778/779 Fax: +84 274 3535 773/774
Email: info@vietglove.vn Website: www.vietglove.vn

No	Standard	Descriptions	Date Published
15	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
16	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
17	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
18	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
19	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4 June 2016
20	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
21	Meddev 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8 January 2013
22	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigiliance	April 2017
23	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
24	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
25	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
26	MEDDEV 2.12/Rec 1	2.12 Post Marketing Surveillance (PMS) post market / production	Revision 11 February 2000
27	MDR 2017/745	Medical Device Regulation	April 2017

Competent Authority : DE/CA09 - Staatliches Gewerbeaufsichtsamt Hannover, Am Listholze, 74, Hannover, Germany.

Basic UDI-DI : 8938508639VietNitrileTA

Date of issue :

Place of issue : Viet Nam

M.S.D.N: 3702160298 - C.T.C.P * CÔNG TY CỔ PHẦN GĂNG VIỆT * H.BÀU BÀNG-T.BÌNH DƯƠNG

Name: Tran Van Hoang

Designation: Quality Management Representative

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

PSB Singapore

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Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

SUBJECT:

Testing of 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

February 17, 2023

▪TEST REPORT▪

PN 168538

Wire Transfer

Chemical/Analytical Services

Prepared For:

Harry Vuong
VietGlove Corp.
Cau Sat Hamlet – Lai Hung Village
Bau Bang District
Bihn Duong
VNM

Prepared by: _____
Yan Xiao, Sr. Chemist
Chemical/Analytical Services

Approved by: _____
Thomas D. Samples, Manager
Chemical/Analytical Services

DCN 1176

www.ardl.com | 2887 Gilchrist Rd. | Akron, OH 44305 | 75 Robinson Ave. | Barberton, OH 44203 | answers@ardl.com
Toll Free (800) 830-ARDL | Fax (330) 794-6610 | Worldwide (330) 794-6600

February 17, 2023
Harry Vuong
VietGlove Corp.

SUBJECT: Analytical testing on sample(s) submitted by customer.

RECEIVED: Viet Glove Corporation Powder Free Nitrile Gloves Code: Alphalink and Viet Glove Corporation Powder Free Nitrile Gloves Code: STM Plus

TESTING LOCATION: All testing performed at our Gilchrist Road location unless otherwise noted

Decision Rule 1

Extractable Chemical Dialkyldithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators in Natural Rubber Latex and Nitrile Gloves; ASTM D7558

SAMPLE PREPARATION:
The glove extract was prepared following the ASTM D7558 requirements in duplicate. The final UV/VIS measurement was performed at 320 nm versus the specified standard solutions as required by the above testing method.

RESULTS:

Sample	Total Accelerator Concentration in Final Leaching Media (MBT, Thiuram and/or Thiocarbamates) (µg/ml)/(µg/g)	Total Accelerator Concentration Available for Leaching From Sample Specimen (MBT, Thiuram and/or Thiocarbamates) (µg/g)
Code Alphalink	None Detected	None Detected
Code STM Plus	None Detected	None Detected

Viet Glove Corporation Powder Free Nitrile Gloves Code: Alphalink and Viet Glove Corporation Powder Free Nitrile Gloves Code: STM Plus

**ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.*

NOTE: The mark ^ is used to designate non-accredited test methods in the body of the report and that any opinions or interpretations for of results for these non-accredited tests are outside the scope of this organization's accreditation

Decision Rules

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands" where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

Report Revision Log

Date	Report Revision	Description
2-17-23	New	

Prepared by: _____
Yan Xiao, Sr. Chemist
Chemical/Analytical Services

Approved by: _____
Thomas D. Samples, Manager
Chemical/Analytical Services

YX/TDS/kas

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-

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

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)*

June 24, 2021

Vietglove Corporation
Terence Lim
Quality Assurance & Regulatory Affairs Manager
Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh
Duong Province
Bingh Duong, Bingh Duong Province 72600
Viet Nam

Re: K201428
Trade/Device Name: Powder Free Black Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LZA
Dated: May 25, 2021
Received: May 27, 2021

Dear 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. 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,

For Ryan Ortega, Ph. D
Acting Assistant Director
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

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."

Monitoring result for VIET GLOVE CORPORATION on site Viet Glove Corp

amfori
Trade with purpose

Monitoring

Monitored Party	: VIET GLOVE CORPORATION
amfori ID	: 704-000431-000
Site	: Viet Glove Corp
Site amfori ID	: 704-000431-002
Address	: Land Lot No.3 Map No. 37, Cau Sat Hamlet, Lai Hung Commune,
	: Bau Bang
	: Lai Châu
	: Vietnam
Monitoring Activity	: amfori Social Audit - Manufacturing
Monitoring Type	: Full Monitoring
Monitoring Partner	: TÜV NORD CERT GmbH
Monitoring Start Date	: 26/12/2022
Closing Meeting Finished Date	: 11/01/2023
Submission Date	: 11/01/2023
Expiration Date	: 11/01/2024

This is an extract of the online monitoring result, generated on 09/02/2023, and is only valid as an acknowledgement of the result. To see all the details, review the full monitoring result, which is available **here** - The English version is the legally binding one.

Overall rating

Section rating

PA1: Social Management System	B
PA 2: Workers Involvement and Protection	A
PA 3: The Rights of Freedom of Association and Collective Bargaining	A
PA 4: No Discrimination	A
PA 5: Fair Remuneration	A
PA 6: Decent Working Hours	A
PA 7: Occupational Health and Safety	D

PA 8: No Child Labour	A
PA 9: Special Protection for Young Workers	A
PA 10: No Precarious Employment	A
PA 11: No Bonded Labour	A
PA 12: Protection of the Environment	A
PA 13: Ethical Business Behaviour	A

“Consistent quality
and high responsiblity”

Vietglove
We care for your life

VIET GLOVE CORPORATION

Add: Plot 03, Map no. 37, Cau Sat Hamlet,
Lai Hung Village, Bau Bang District, Binh Duong, Vietnam
Tel: +84 274 3535 778/779 | Fax: +84 274 3535 773/774
Tax Code: 3702150298 | Email: info@vietglove.vn