VRG KHAI HOAN JSC

ISO 9001:2015; ISO 13485:2016;

FDA 510K to American Market,

CE Marking to *European Market,*

Ministry of Health and *QUATEST3 Certificates*

CE
NL/CAO1/601529
CE Marking

KHAI HOAN GLOVES

VGLOVE

PRODUCT LINES

- NITRILE
  (powdered/ powder free)
- LATEX
  (powdered/ powder free)
- STERILIZED SURGICAL GLOVES

bsi. ISO 13485 Medical Devices Quality Management

bsi. HACCP & GMP Food Safety Management

bsi. ISO 22000 Food Safety System Certification

bsi. ISO 9001 Quality Management

BSI ANAB
ISO 9001:2015

FDA 510K Cleared Medical Devices
FDA 510K

ISO SA8000

QUATEST3

BO Y TE
Free Sale's Certificate

BO Y TE
Circulation Certificate

Mr. Long (+84) 91 186 1119

VRG KHAI HOAN JSC

POWDER FREE GLOVES

PRODUCT INFORMATION

VGLOVE

NITRILE GLOVES
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	
	VRG KHAI HOAN	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	

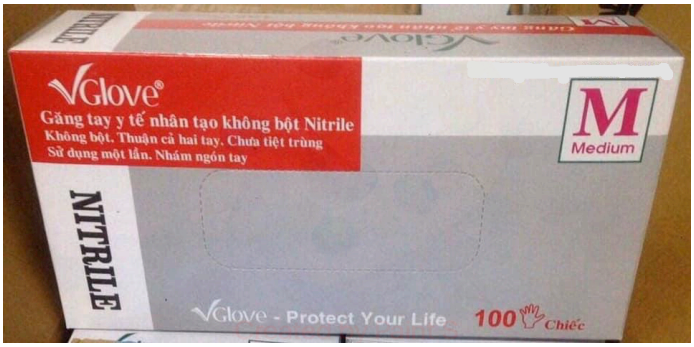
Mr. Long (+84) 91 186 1119

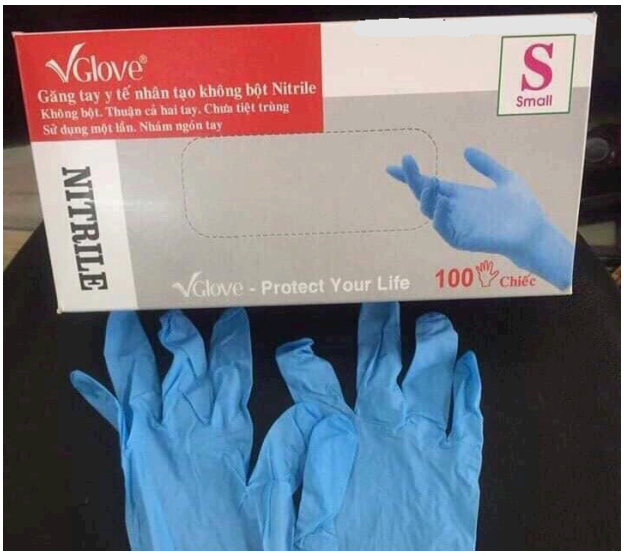
VRG KHAI HOAN JSC

POWDER FREE GLOVES

PRODUCT PICTURES

VGLOVE





SPECIFICATIONS FOR CARTON

Dimension: 360 mm x 260 mm x 240 mm
Weight: ~4 kg/carton
Quantity: 10 boxes/carton

Mr. Long (+84) 91 186 1119

VRG KHAI HOAN JSC

PRODUCT CERTIFICATES - GMP

bsi.

By Royal Charter

Certificate of Registration

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that: **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune, Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **BSIVN 1313/2019**

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

The manufacture and distribution of:
- Non-sterile, powder, powder free natural latex examination gloves.
- Non-sterile, powder free nitrile examination gloves.

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

Original Registration Date: **10/06/2019**
Latest Revision Date: **10/06/2019**
Effective Date: **10/06/2019**
Expiry Date: **09/06/2022**

Page: 1 of 1

...making excellence a habit.

bsi.

By Royal Charter

Giấy Chứng Nhận

THỰC HÀNH SẢN XUẤT TỐT – GMP

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng, Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **BSIVN 1313/2019**

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

Sản xuất và phân phối:
- Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột.
- Găng tay nitrile y tế không tiệt trùng, không bột.

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

Ngày đăng ký đầu tiên: **10/06/2019**
Ngày sửa đổi sau cùng: **10/06/2019**
Ngày hiệu lực: **10/06/2019**
Ngày hết hiệu lực: **09/06/2022**

Trang 1/1

...making excellence a habit.

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **FM 548618**

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, powder free natural latex examination gloves;
Non-sterile, powder free nitrile examination gloves.

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

Original Registration Date: **01/06/2009**
Latest Revision Date: **30/05/2018**

Effective Date: **01/06/2018**
Expiry Date: **31/05/2021**

...making excellence a habit"

bsi.

By Royal Charter

Certificate of Registration

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

This is to certify that: **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **MD 548620**

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 natural latex examination gloves;
Non-sterile, powder free nitrile examination gloves.

For and on behalf of BSI: Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: **18/05/2009**
Latest Revision Date: **02/05/2018**

Effective Date: **18/05/2018**
Expiry Date: **17/05/2021**

Page: 1 of 1

...making excellence a habit.

bsi.

By Royal Charter

Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2005

This is to certify that: **VRG KHAI HOAN JOINT STOCK COMPANY**
Cau Sat Hamlet,
Lai Hung Commune,
Bau Bang District,
Binh Duong Province,
Vietnam

Holds Certificate Number: **FSMS 552546**

and operates a Food Safety Management System which complies with the requirements of ISO 22000:2005 for the following scope:

The manufacture and distribution of:
Non-sterile, powder, powder free natural latex examination gloves;
Non-sterile, powder free nitrile examination gloves.

Category: I

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

Original Registration Date: **09/10/2009** Effective Date: **09/10/2018**
Latest Revision Date: **14/07/2018** Expiry Date: **18/06/2021**

Page: 1 of 1

...making excellence a habit.

bsi.

By Royal Charter

Giấy Chứng Nhận

HỆ THỐNG TRÁCH NHIỆM XÃ HỘI - SA 8000:2014

Xác nhận rằng:

CÔNG TY CỔ PHẦN VRG KHẢI HOÀN
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **SA 598117**

và thực hiện Hệ thống Trách Nhiệm Xã Hội phù hợp với các yêu cầu của Tiêu Chuẩn Trách Nhiệm Xã Hội SA 8000:2014 cho phạm vi:

Sản xuất và phân phối găng tay y tế cao su có bột và không bột, găng tay cao su nitrile bao gồm các quá trình tiếp nhận nguyên vật liệu latex/ nitrile, phối trộn, tạo đông, lưu hóa, tách chiết, nhúng bột bắp/chlorine, sấy khô, kiểm tra và đóng gói.

Các quá trình gia công ngoài: Không.
Các quá trình hợp đồng ngoài: Không.

Đại diện cho tập đoàn BSI: *Tổng Giám Đốc BSI Ấn Độ, Venkataram Arabolu*

Ngày đăng ký đầu tiên: **19/11/2013**
Ngày sửa đổi sau cùng: **11/11/2019**

Ngày hiệu lực: **19/11/2019**
Ngày hết hiệu lực: **18/11/2022**

...making excellence a habit.

Australia | Canada | China | Japan | The Netherlands | United States

EMERGO EUROPE

26 May 2009

Mr. Terence Lim
Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong
Vietnam

Dear Terence:

I am writing to inform you that today, we have notified by registered mail the Dutch Competent Authority.

With this notification, Khai Hoan Joint Stock Company has met the requirements of Article 14 of the Medical Devices Directive, 93/42/EEC for the following devices:

- **Powder Examination Gloves**
- **Powder-Free Examination Gloves**

As of today and without any further notice from the respective Competent Authorities, Khai Hoan Joint Stock Company can consider the respective devices and Authorized Representative as officially registered.

If you have any questions, please do not hesitate to contact me.

Yours sincerely,

Rene van de Zande
President & CEO

EmergoEurope.com

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299

Australia | Canada | China | Japan | The Netherlands | United States

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

Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong Province
Vietnam

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

EmergoEurope.com

Emergo Europe Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570 Fax: +31.70.346.7299

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 23 2010

Mr. Terence Lim
Quality Assurance Manager
Khai Hoan Joint Stock Company
Cau Sat Hamlet, Lai Hung Commune, Ben Cat District
Binh Duong Province
VIETNAM

Re: K092681
Trade/Device Name: Powdered Latex Examination Gloves (Non-Colored)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: January 14, 2010
Received: January 19, 2010

Dear Mr. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SATRA TECHNOLOGY

Issued to:

VRG Khai Hoan JSC
Cau Sat Hamlet
Lai Hung Commune
Bau Bang District
Binh Duong Province
Vietnam

Notified Body: 2777

SATRA customer number: P1434

EU Type-Examination Certificate

Certificate number: 2777/11582-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference: PFNBR

Description: Non-sterile powder free nitrile examination gloves

Sizes: XS/6, S/7, M/8, L/9, XL/10

Classification:

EN ISO 374-1: 2016 / Type B	**Level**	**EN ISO 374-4:2013 % Degradation**
40% Sodium hydroxide (K)	6	-13.2
30% Hydrogen peroxide (P)	4	5.3
37% Formaldehyde (T)	6	4.6
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0225034/1420/2, SPC0225034/1420/SMcD/B, SPC0244727/1615, CHM0248775/1632/SMcD, CHM0272778/1827/LH, CHM0276386/1840/JH, SPC0244727/1615, SPC0273658/1830, CHM0273594/1830/LH/A, CHM0273594/1830/LH/B, CHM0273594/1830/LH/C
TUV: 7191169844-CHM17-01-RC

Signed on behalf of SATRA: Tara Saunders Austin Simmons

Date first issued: 23/11/2018
Date of issue: 23/11/2018

Expiry date: 23/11/2023

Mr. Long (+84) 91 186 1119

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.

Mr. Long (+84) 91 186 1119

KHAI HOAN JOINT STOCK COMPANY
Cau Sat Hamlet, Lai Hung Commune, Ben Cat District, Binh Duong Province, Vietnam

Indications for Use

Applicant : KHAI HOAN JOINT STOCK COMPANY

510(k) Number (if known): K092681

Device Name: POWDERED LATEX EXAMINATION GLOVES (NON-COLORED)

Indications for Use:

Powder Natural Rubber Latex Examination Glove is a non-colored, single use device intended for medical purposes that is worn on the hand of medical personnel to prevent contamination between the patient and examiner.

Prescription Use ____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092681

QUATEST 3®

TỔNG CỤC TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG
DIRECTORATE FOR STANDARDS AND QUALITY

TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3
QUALITY ASSURANCE AND TESTING CENTER 3

GIẤY CHỨNG NHẬN
CERTIFICATE

Số / *No.*: 12-07
(KH1-CNL-2019)

Chứng nhận sản phẩm / *This is to certify that:*

GĂNG TAY CAO SU Y TẾ / MEDICAL RUBBER GLOVES

Nhãn hiệu / *Brand name:* VGlove Protect Your Life

Loại / *Types:* Không tiệt trùng loại I, có bột hoặc không có bột / *Non- sterile Type I, Powdered or Powder free*

Kích cỡ / Sizes: 75, 83, 89, 95, 108, 114 (mm)

Được sản xuất tại / *Manufactured at:* **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN / VRG KHAI HOAN JOINT STOCK COMPANY**

Địa chỉ: Thửa đất số 233, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương /

Address: Land parcel No. 233, Map No. 37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province

Phù hợp với tiêu chuẩn / *Conforms to the standard:* **ASTM D 3578-05**

Standard Specification for Rubber Examination Gloves

Phương thức chứng nhận / *Certification scheme:*

Phương thức 5 / *Scheme 5*

(Thông tư số 28/2012/TT-BKHCN ngày 12/12/2012 và Thông tư số 02/2017/TT-BKHCN ngày 31/3/2017 của Bộ Khoa học và Công nghệ)

(Circular No. 28/2012/TT-BKHCN dated December 12th 2012 and Circular No. 02/2017/TT-BKHCN dated March 31st 2017 of Ministry of Science and Technology)

Giấy chứng nhận này có giá trị từ 04/5/2019 đến 03/5/2022

The certificate remains valid from May 04th, 2019 to May 03rd, 2022

QUATEST 3
ASTM D 3578-05

KT. GIÁM ĐỐC / *FOR DIRECTOR*
PHÓ GIÁM ĐỐC / VICE DIRECTOR

TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3

Mai Văn Sủng

Trung tâm Kỹ thuật Tiêu chuẩn Đo lường Chất lượng 3
Quality Assurance and Testing Center 3

49 Pasteur, Quận 1, Tp.Hồ Chí Minh
49 Pasteur, District 1, Ho Chi Minh City

Tel: (84-28) 3829 4274
Tel: (84-28) 3829 4274

Fax: (84-28) 3829 3012
Fax: (84-28) 3829 3012

Mr. Long (+84) 91 186 1119

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
Hà nội, ngày 02 tháng 10 năm 2019

GIẤY CHỨNG NHẬN LƯU HÀNH TỰ DO
CERTIFICATE OF FREE SALES

1. Giấy chứng nhận số: 43 **/CFS/BYT-TB-CT**
- Certificate No:
2. Sản phẩm: Găng tay khám bệnh.
- Product(s): Nitrile examination gloves
3. Chủng loại/Model: KHPFNT
4. Công ty sở hữu hợp pháp: Công ty Cổ phần VRG Khải Hoàn.
- Product(s) Owner: VRG Khai Hoan Joint Stock Company.
- Địa chỉ: Thửa đất số 233, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương, Việt Nam.
- Address of Head Office: Land parcel No.233, Map No.37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Viet Nam.
5. Công ty sản xuất: Công ty Cổ phần VRG Khải Hoàn.
- Manufacturer: VRG Khai Hoan Joint Stock Company.
- Địa chỉ: Thửa đất số 233, Tờ bản đồ số 37, Ấp Cầu Sắt, Xã Lai Hưng, Huyện Bàu Bàng, Tỉnh Bình Dương, Việt Nam.
- Address of Head Office: Land parcel No.233, Map No.37, Cau Sat Hamlet, Lai Hung Commune, Bau Bang District, Binh Duong Province, Viet Nam.

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.

Giấy chứng nhận này có hiệu lực 03 năm kể từ ngày ký.
This certificate is valid for three years from the date of issuance.

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