

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



NL/CA01/601529
CE Marking



QUATEST3
ALTB 0 3678-02



Free Sale's Certificate



Circulation Certificate

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑



VRG Khai Hoan JSC, earlier known as Khai Hoan JSC was established in 2006, specializes in manufacturing high quality medical examination gloves to supply for both local and export market. We are proud to be one of leading gloves manufacture of Vietnam and the world. At the present, our main products are Latex examination powder and powder free gloves. Besides that we are producing sterile latex surgical gloves for local market and for oversea market in the future. Annually VRG Khai Hoan delivers more than 8 billion pieces of gloves to domestic as well as oversea market. Our main markets are: Asia, Europe, America, Africa, and Latin America and other countries.

Khai Hoan have been upgrading our quality management system, services and diversifying products. We have applied and are maintaining a quality management system ISO 9001: 2015, ISO 13485: 2016 and food safety quality management system ISO 22000:2005 for our products. At the same time, we are honored to receive the FDA 510K Certificate, CE Certificate, Certificate from Ministry of health in Viet Nam and conformity Certificate from quatest 3 in Viet Nam. Therefore, customers completely assured about our products. Khai Hoan looking forward to be better served the demand of domestic gloves and become one of the leading of gloves manufacturers in the region and on the world.

COVID-19

Vglove Non-sterile Powder-free Latex gloves

코로나 Vglove 비멸균 라텍스 의료용 장갑



PRODUCT (품명)	Vglove Non-sterile Powder Free Latex Examination Gloves				
HS CORD	4015.19-0000				
Quality Standards (인증)	FDA510K, CE, ISO, EN, GMP, QUATEST3				
PACKING (입수)	100pcs (inner) / 10 inners (carton)				
Box Size (mm)	Inner 230*125*75 (100pcs) Carton 340x250x240 (1,000pcs)				
Carton CBM 0.0204 (컨테이너 입수)	20ft about 1,000 ct (1,000,000pcs) 40ft about 2,500 ct (2,500,000pcs)				
Dimension (mm) / (사이즈)	Size	Palm Width	Length		
	S	< 80	min 240		
	M	85 ± 3	min 240		
	L	95 ± 3	min 240		
	XL	105 ± 3	min 240		
Thickness (두께)	0.10 mm				
Weight (gram) Tolerance ± 0.3gr (무게)	Size	Weight			
	S	4.0			
	M	5.0			
	L	6.0			
	XL	7.0			
Output (생산량)	1 day : 5,000,000 pcs Special 10 day : 100 million pcs				
Payment method (결재방법)	50% prepayment 50% cash deposit before delivery				
Vietnam FOB (출고조건)	Air : Tan Son Nhat				
	Shippment : CAT LAI				

COVID-19

Vglove Non-sterile Powder-free Nitrile gloves

코로나 Vglove 비멸균 니트릴 의료용 장갑

PRODUCT (품명)	Vglove Non-sterile Powder Free Nitrile Gloves				
HS CORD	4015.19-0000				
Quality Standards (인증)	FDA510K, CE, ISO, EN, GMP, QUATEST3				
PACKING (입수)	100pcs (inner) / 10 inners (carton)				
Box Size (mm)	Inner 230*125*75 (100pcs)				
	Carton 340x250x240 (1,000pcs)				
Carton CBM 0.0204 (컨테이너 입수)	20ft about 1,000 ct (1,000,000pcs)				
	40ft about 2,500 ct (2,500,000pcs)				
Dimension (mm) ± 0.5 / (사이즈)	Size	Palm Width	Length		
	S	83	280		
	M	89	280		
	L	95	280		
	XL	102	280		
Thickness (두께)	0.10 mm				
Weight (gram) Tolerance ± 0.3gr (무게)	Size	Weight			
	S	3.5			
	M	4.0			
	L	4.5			
	XL	5.0			
Output (생산량)	1 day : 5,000,000 pcs Special 10 day : 100 million pcs				
Payment method (결재방법)	50% prepayment 50% cash deposit before delivery				
Vietnam FOB (출고조건)	Air : Tan Son Nhat				
	Shipment : CAT LAI				



COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification / FDA 510K_K092681



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



FDA 510K

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification referenced above and have determined the device is suitable (based on the information provided and the intended indications for use stated in the enclosure) to legally market the device in interstate commerce prior to May 28, 1976, the enactment of the Medical Device Amendments, or to devices that have been reclassified under the Federal Food, Drug, and Cosmetic Act (Act) that do not require premarket approval application (PMA). You may, therefore, market the device under the general controls provisions of the Act. The general controls provide for requirements for annual registration, listing of devices, labeling, and prohibitions against misbranding and adulteration. FDA does not evaluate information related to contract liability when determining whether a device is suitable. However, the device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II or class III (PMA), it may be subject to additional controls. Existing controls for class II devices are described in the Code of Federal Regulations, Title 21, and class III devices are described in the PMA. In addition, FDA may publish further announcements concerning the classification of your device. You may register your device with FDA at [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](#).

510(k) Premarket Notification

[New Search](#) [Back To Search Results](#)

Device Classification Name	Latex Patient Examination Glove
510(K) Number	K092681
Device Name	POWDERED LATEX EXAMINATION GLOVES, NON-STERILE
Applicant	KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN
Applicant Contact	Pham N Thanh KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN
Correspondent Contact	Pham N Thanh 880.6250
Regulation Number	LYY
Classification Product Code	LYY
Date Received	09/01/2009
Decision Date	02/23/2010
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Page Last Updated: 04/27/2020
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FDA

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

Combination Products
Advisory Committees
Science & Research
Regulatory Information

U.S. Department of Health & Human Services



COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification / FDA 510K_K113685



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

Khai Hoan Joint Stock Company
C/O Mr. Terence Lim
Quality Assurance & Regulatory Affairs Manager
Cau Sat Hamlet, Lai Hung Commune
Ben Cat District, Binh Duong Province
Vietnam

AUG 10 2012

Re: K113685
Trade/Device Name: Powder-Free Latex Examination Gloves with Protein Content
Labeling Claim of 50 µg/dm² or Less
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: April 20, 2012
Received: July 23, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification referenced above and have determined the device (indications for use stated in the enclosure) to be new (not in commercial distribution in the United States) and not subject to the Federal Food, Drug, and Cosmetic Act (Act) (Amendments, or to devices that have been reclassified under the Federal Food, Drug, and Cosmetic Act (Act) approval application (PMA). You may, therefore, rely on the general controls provisions of the Act. The general controls provisions for annual registration, listing of devices, labeling, and prohibitions against misbranding are not evaluated information related to contract liability. The device labeling must be truthful and not misleading.

If your device is classified (see above) into either a PMA, it may be subject to additional controls. The device can be found in the Code of Federal Regulations. In addition, FDA may publish further announcements. [Register](#).



FDA 510K

510(k) Premarket Notification

FDA Home | Medical Devices | Databases

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

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Device Classification Name	Latex Patient Examination Glove
510(K) Number	K113685
Device Name	POWDER FREE LATEX EXAMINATION GLOVES
Applicant	KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN Vm
Applicant Contact	Terence Lim
Correspondent	KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN Vm
Correspondent Contact	Terence Lim
Regulation Number	880.6250
Classification Product Code	LYY
Date Received	12/15/2011
Decision Date	08/10/2012
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Statement	Statement
Type	Traditional
Reviewed By Third Party	No
Combination Product	No



ISO 9001:2008

ISO 13485:2003

ISO 22000:2005

FDA 510K



CE Marking

QUATEST3

Free Sale's Certificate

Circulation Certificate

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Combination Products
Advisory Committees
Science & Research
Regulatory Information

U.S. Department of Health & Human Services

COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑 Certification / CE

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

ISO 9001:2008 ISO 13485:2003 ISO 22000:2005 FDA 510K

CE Marking QUATEST3 Free Sale's Certificate Circulation Certificate



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

NL/CA01/601529

EmergoEurope.com

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

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification

EN ISO 13485:2016 / 22000:2005



Certificate of Registration



By Royal Charter

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 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 – Medic

Original Registration Date: **18/05/2009**

Effective Date

Latest Revision Date: **02/05/2018**

Expiry Date: 1

**MD 548620**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, Tel: +44 845 080 9000. BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of the BSI Group of Companies.



Certificate of Registration



By Royal Charter

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

FSMS 552546

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


Chris Cheung, Head of Compliance & Risk – Asia Pacific

For and on behalf of BSI:

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

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ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



CE Marking



QUATEST3



Free Sale's Certificate



Circulation Certificate

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification ISO 9001:2015



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

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**

Effective Date: **01/06/2018**

Latest Revision Date: **30/05/2018**

Expiry Date: **31/05/2021**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000. BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of the BSI Group of Companies.



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



CE Marking



QUATEST3



Free Sale's Certificate



Circulation Certificate

<https://www.emergobyul.com/>

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification SA 8000



By Royal Charter



Certificate of Registration

SOCIAL ACCOUNTABILITY SYSTEM - SA 8000:2014

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:

SA 598117

SA 598117

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 non-sterile powder, powder free latex and nitrile examination glove through the process of receiving rubber latex/ nitrile, compounding, coagulating, vulcanising, leaching, slurry/ chlorine dipping, drying, testing, packing and despatch.

Outsourced processes: Nil
Contracted processes: Nil



For and on behalf of BSI:

Managing Director, BSI India, Venkataswamy

Original Registration Date: **19/11/2013**

Effective Date: **19/11/2019**

Latest Revision Date: **11/11/2019**

Expiry Date: **18/11/2022**

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ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



ISO 22000:2005



FDA 510K



CE Marking



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Free Sale's Certificate



Circulation Certificate

<https://www.emergobyul.com/>

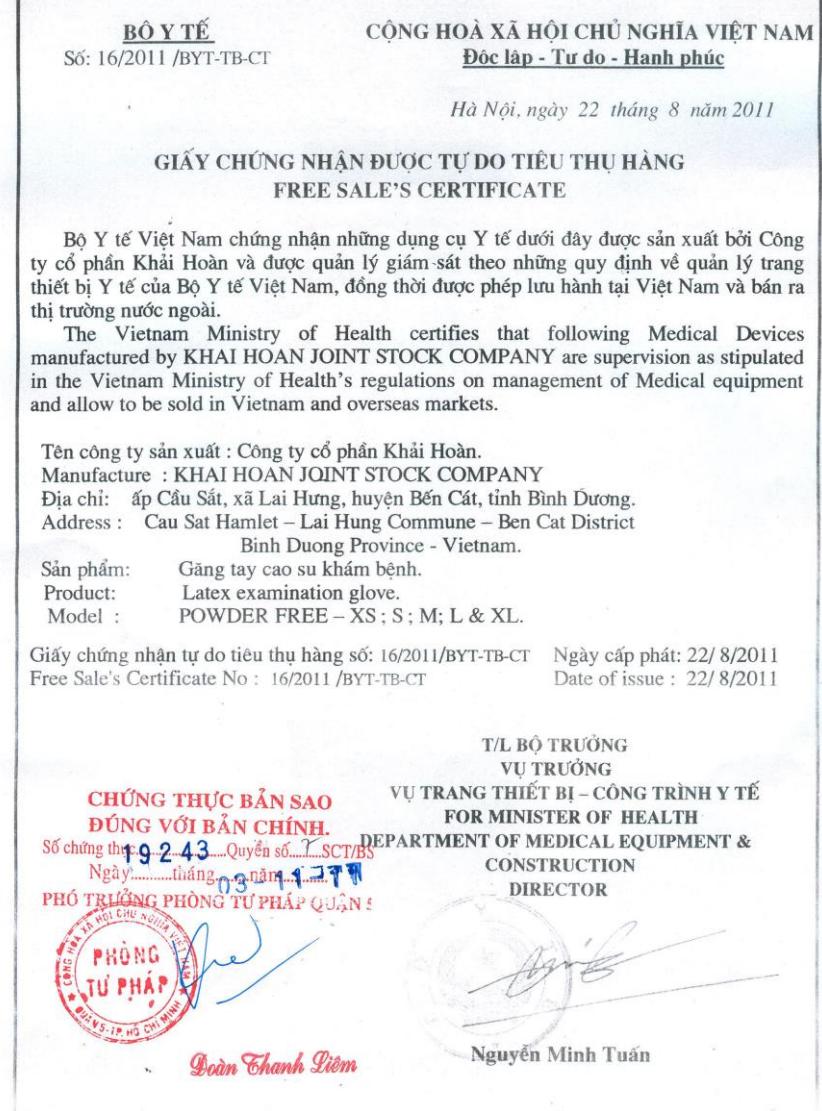
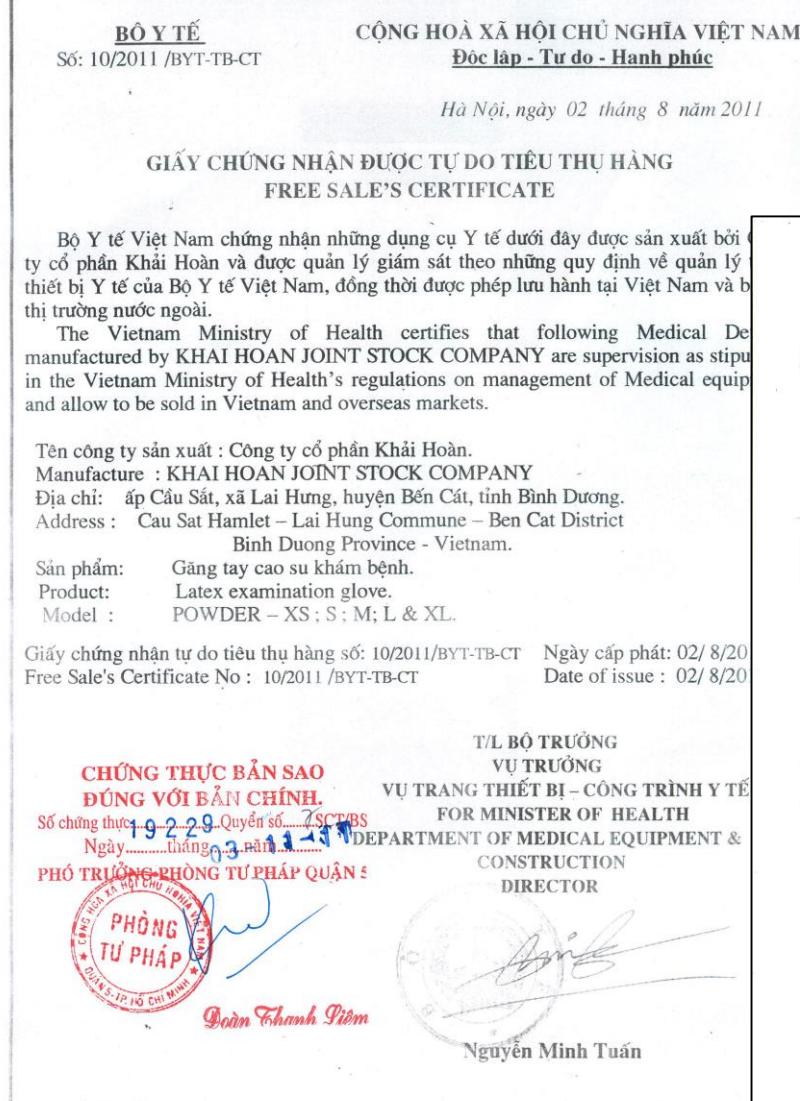
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Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Vietnam Ministry of Health certified

베트남 보건부 의료기기 국내외 판매허가서



COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Vietnam QUATEST3

시험성적서



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 / №.: 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



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 Fax: (84-28) 3829 3012

Trang / page 1/1



Mai Văn Sùng



ISO 9001:2008



Accredited



ISO 13485:2003



UKAS Quality Management



ISO 22000:2005



510K Cleared
Medical Devices



CE Marking



QUATEST3



Free Sale's Certificate



Circulation Certificate

Vglove Non-sterile Powder-free Latex / Nitrile gloves
 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑
**REGISTRATION FOR CIRCULATION OF
 MEDICAL DEVICE MANUFACTURING IN VIETNAM**

베트남 의료 기기 제조허가증

BỘ Y TẾ

Số (No) 15/2011/BYT-TB-CT

Hà Nội, ngày (date): 06/5/2011

**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 DEVICE MANUFACTURING IN VIETNAM

- Căn cứ Luật Chất lượng sản phẩm, hàng hoá ngày 21/11/2007.
Based on Law on Quality of products and goods dated November 21, 2007.
- Căn cứ Thông tư số 07/2002/TT-BYT ngày 30/5/2002 của Bộ Y tế
 về hướng dẫn đăng ký lưu hành sản phẩm Trang thiết bị y tế.
Based on Circular Letter 07/2002/TT-BYT dated May 30, 2002 of the Ministry of Health on guiding for circulation registration of medical device.
- 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

Đơn vị (Company): CÔNG TY CỔ PHẦN KHẢI HOÀN

Địa chỉ (Address): Ấp Cầu sắt, xã Lai Hưng, huyện Bến cát,
 tỉnh Bình Dương

Điện thoại (Tel): 0650 3591220 Fax: 06503591225

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

- Tên sản phẩm: GĂNG TAY CAO SU Y TẾ
 (Name of the product)

- Ký mã hiệu sản phẩm: KHPPEX, KHPFEX, KHPSS
 (Model and Serial number)

- Tiêu chuẩn công bố: ASTM D 3578-05
 (Conform to the Standards of)

- Số đăng ký lưu hành được cấp: 15/2011/BYT-TB-CT
 (Registered number)



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



CE Marking



QUATEST3



Free Sale's Certificate



Circulation Certificate