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

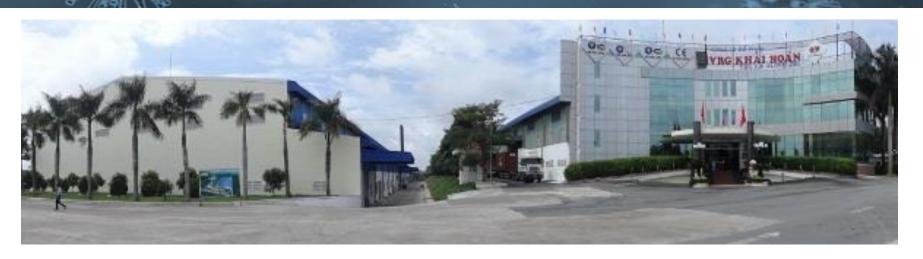








COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑











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	
	М	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		
	М		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	
	М	89		280	
	L	95		280	
	XL	102		280	
Thickness (두께)	0.10 mm				
Weight (gram) Tolerance ± 0.3gr (무게)	Size		Weight		
	S		3.5		
	М		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				
V° (Air: Tan Son Nhat				
Vietnam FOB (출고조건)	shippment: CAT LAI				























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 2 3 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

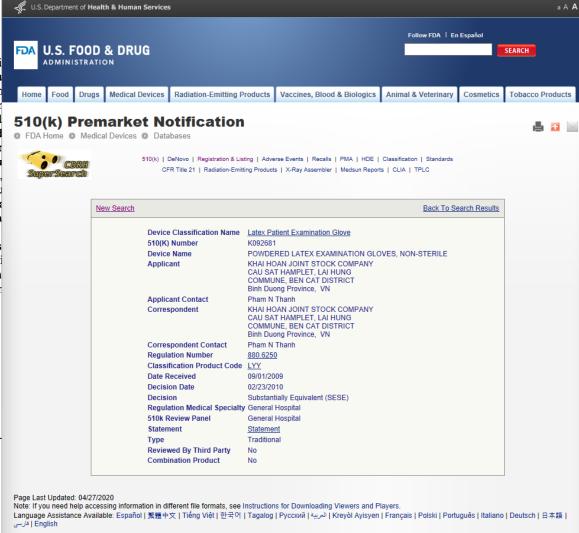
Regulatory Class: I Product Code: LYY Dated: January 14, 2010 Received: January 19, 2010

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket noti referenced above and have determined the device is su indications for use stated in the enclosure) to legally m interstate commerce prior to May 28, 1976, the enactm Amendments, or to devices that have been reclassified the Federal Food, Drug, and Cosmetic Act (Act) that d approval application (PMA). You may, therefore, mar controls provisions of the Act. The general controls pr requirements for annual registration, listing of devices, labeling, and prohibitions against misbranding and adu not evaluate information related to contract liability wa that device labeling must be truthful and not misleadin

If your device is classified (see above) into either class (PMA), it may be subject to additional controls. Exist device can be found in the Code of Federal Regulation addition, FDA may publish further announcements cor Register.





Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrim

Advisory Committees Science & Research





















U.S. Food and Drug Administration

Ph. 1-888-INFO-FDA (1-888-463-6332)

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 1 0 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 Examnation 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) premarke referenced above and have determined the device indications for use stated in the enclosure) to lega interstate commerce prior to May 28, 1976, the e Amendments, or to devices that have been reclas the Federal Food, Drug, and Cosmetic Act (Act) approval application (PMA). You may, therefore controls provisions of the Act. The general contr requirements for annual registration, listing of de labeling, and prohibitions against misbranding ar not evaluate information related to contract liabil that device labeling must be truthful and not misl

If your device is classified (see above) into either (PMA), it may be subject to additional controls. device can be found in the Code of Federal Regu addition, FDA may publish further announcemer Register.



510(k) Premarket Notification

e

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

Back To Search Results New Search Device Classification Name Latex Patient Examination Glove 510(K) Number K113685 **Device Name** POWDER FREE LATEX EXAMINATION GLOVES KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN Vm Applicant Contact Terence Lim KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMPLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN Vm Correspondent Contact Terence Lim 880.6250 Classification Product Code LYY 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 Combination Product





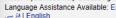












Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | أسريبة | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | 비교



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

Advisory Committees Science & Research

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players





COVID-19

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

Certification / CE



26 May 2009

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

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 Joir 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























EMERGO BEUROPE

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:

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



President & CEO Emergo Europe

NL/CA01/601529

EmergoEurope.com

Molenstraat 15, 2513 BH The Hague, The Netherlands Telephone: +31.70.345.8570

Certification ISO 13485:2016 / 22000:2005

bsi.

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 1 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 - Medic

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

Effective Date Expiry Date:





MD 548620

...making exce

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated online, Printed copies can be validated at www.bsigroup.com/Client Directory or telluring clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirement the organization. This certificate is valid only if provided original capies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MKS 8PP. Tcl: + 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.



















bsi.



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,

Holds Certificate Number:

FSMS 552546

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:

Original Registration Date: 09/10/2009 Latest Revision Date: 14/07/2018

Effective Date: 09/10/2018 Expiry Date: 18/06/2021





Page: 1 of 1

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cate was issued electronically and remains the property of BSI and is bound by the conditions of contract. iic certificate can be authenticated <u>online</u>, Printed copies can be validated at https://www.bsigroup.com/Client Directrifications regarding the scope of this certificate and the applicability of ISO 22000:2005 requirements m.n. This certificate is valid only if provided original copies are in complete set.

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.

glove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

Certification ISO 9001:2015







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 Latest Revision Date: 30/05/2018

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

Page: 1 of 1







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https://www.emergobyul.com/

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

Certification SA 8000







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, Venkataram Arabolu

Effective Date: 19/11/2019 Original Registration Date: 19/11/2013 Expiry Date: 18/11/2022 Latest Revision Date: 11/11/2019





Page: 1 of 1

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pertificate can be authenticated online. Printed copies can be validated at <a href="www.bsi-global.com/Client Directory or telephone" +91 11 2692 9000. ations regarding the scope of this certificate and the applicability of SA 8000: 2014 requirements may be obtained by consulting the organization. This certificate in complete set. onic certificate can be authenticated online. Printed copies can be validated at www.bsi-global.com/Client Dire

Accountability International and other stakeholders in the SA 8000 process only recognize SA 8000 certificates issued by qualified Certification not recognize the validity of SA 8000 certificates issued by unaccredited organizations or organizations accredited by an entity other the

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 Compa



















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Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑 ietnam Ministry of Health certified

BÔ Y TẾ Số: 10/2011 /BYT-TB-CT

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM Độc lập - Tư do - Hanh phúc

Hà Nội, ngày 02 tháng 8 năm 2011

GIẤY CHÚNG NHẬN ĐƯỢC TỰ DO TIÊU THỤ HÀNG FREE SALE'S CERTIFICATE

Bộ Y tế Việt Nam chứng nhận những dụng cụ Y tế dưới đây được sản xuất bởi ty cổ phần Khải Hoàn và được quản lý giám sát theo những quy định về quản lý thiết bị Y tế của Bộ Y tế Việt Nam, đồng thời được phép lưu hành tại Việt Nam và b thị trường nước ngoài.

The Vietnam Ministry of Health certifies that following Medical De manufactured by KHAI HOAN JOINT STOCK COMPANY are supervision as stipu in the Vietnam Ministry of Health's regulations on management of Medical equip and allow to be sold in Vietnam and overseas markets.

Tên công ty sản xuất : Công ty cổ phần Khải Hoàn. Manufacture : KHAI HOAN JOINT STOCK COMPANY

Địa chỉ: ấp Cầu Sắt, xã Lai Hưng, huyện Bến Cát, tỉnh Bình Dương. Address: Cau Sat Hamlet - Lai Hung Commune - Ben Cat District

Binh Duong Province - Vietnam.

Sản phẩm:

Găng tay cao su khám bệnh. Latex examination glove.

Product: Model:

POWDER - XS; S; M; L & XL

Giấy chứng nhận tự do tiêu thụ hàng số: 10/2011/BYT-TB-CT

Free Sale's Certificate No: 10/2011 /BYT-TB-CT

Ngày cấp phát: 02/8/20 Date of issue: 02/8/20

CHỨNG THỰC BẨN SAO ĐÚNG VỚI BẨN CHÍNH.

VII TRANG THIẾT BI - CÔNG TRÌNH V TẾ FOR MINISTER OF HEALTH Số chứng thực 9 2 2 9 Quyển số 7 SCTBS FOR MINISTER OF HEALTH
Ngày hếng 3 năm 1 1 DEPARTMENT OF MEDICAL EQUIPMENT &
PHÓ TRƯỚNG PHÒNG TƯ PHÁP QUẬN 5

PHÓ TRƯỚNG PHÒNG TỪ PHÁP QUẬN 5

PHÔNG TU PHÁP

Dogn Chanh Diem

Nguyễn Minh Tuấn

T/L BỘ TRƯỞNG

VU TRƯỞNG

DIRECTOR

베트남 보건부 의료기기 국내외 판매허가서

BÔ Y TẾ Số: 16/2011 /BYT-TB-CT CÔNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM Độc lập - Tư do - Hanh phúc

Hà Nội, ngày 22 tháng 8 năm 2011

GIẤY CHỨNG NHẬN ĐƯỢC TỰ DO TIÊU THỤ HÀNG FREE SALE'S CERTIFICATE

Bộ Y tế Việt Nam chứng nhận những dụng cụ Y tế dưới đây được sản xuất bởi Công ty cổ phần Khải Hoàn và được quản lý giám sát theo những quy định về quản lý trang thiết bị Y tế của Bộ Y tế Việt Nam, đồng thời được phép lưu hành tại Việt Nam và bán ra

thị trường nước ngoài.

The Vietnam Ministry of Health certifies that following Medical Devices manufactured by KHAI HOAN JOINT STOCK COMPANY are supervision as stipulated in the Vietnam Ministry of Health's regulations on management of Medical equipment and allow to be sold in Vietnam and overseas markets.

Tên công ty sản xuất : Công ty cổ phân Khải Hoàn. Manufacture : KHAI HOAN JOINT STOCK COMPANY

Địa chỉ: ấp Cầu Sắt, xã Lai Hưng, huyện Bến Cát, tỉnh Bình Dương. Address: Cau Sat Hamlet - Lai Hung Commune - Ben Cat District

Binh Duong Province - Vietnam. Sản phẩm: Găng tay cao su khám bệnh.

Product:

Latex examination glove.
POWDER FREE – XS; S; M; L & XL. Model:

Giấy chứng nhận tự do tiêu thụ hàng số: 16/2011/BYT-TB-CT Ngày cấp phát: 22/8/2011 Free Sale's Certificate No: 16/2011 /BYT-TB-CT Date of issue: 22/8/2011

> T/L BỘ TRƯỞNG VỤ TRƯỞNG

CHỨNG THỰC BẨN SAO

VU TRANG THIẾT BI - CÔNG TRÌNH Y TẾ FOR MINISTER OF HEALTH ĐÚNG VỚI BẨN CHÍNH. Số chứng thực 9 2 43 Quyển số SCT DEPARTMENT OF MEDICAL EQUIPMENT & CONSTRUCTION

Ngày tháng 3 năm 4 277 PHÓ TRƯỜNG PHÒNG TƯ PHÁP QUẬN !

PHONG TU PHÁP

Doàn Thanh Liêm

Nguyễn Minh Tuấn

DIRECTOR



















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

Vietnam QUATEST3



TÔNG 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 TÉ / MEDICAL RUBBER GLOVES

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



Kỹ thuật Tiêu chuẩn Đo lường Chất lượng 3 surance and Testing Center 3

KT. GIÁM ĐỐC I FOR DIRECTOR-PHÓ GIÁM ĐÓC / VICE DIRECTOR DO LUCING

Mai Văn Sủng

Tel: (84-28) 3829 4274 Fax: (84-28) 3829 3012 Tel: (84-28) 3829 4274 Fax: (84-28) 3829 3012 Trang / page 1/1





















시험성적서

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

BÔ Y TẾ

Hà Nội, ngày (date): 06/5/2011

Số (No) 15/2011/BYT-TB-CT

GIẤY CHÚNG 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 CHÚNG 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

Diên thoai (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)

KHPPEX, KHPFEX, KHPPSS

Ký mã hiệu sản phẩm:
 (Model and Serial number)

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

Số đăng ký lưu hành được cấp:

15/2011/BYT-TB-CT

(Registered number)

















