

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



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 (결제방법)	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 (결제방법)	50% prepayment 50% cash deposit before delivery		
Vietnam FOB (출고조건)	Air : Tan Son Nhat		
	shippment : 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



Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification (referenced above and have determined the device is suitable for use in interstate commerce prior to May 28, 1976, the enactment of the Food, Drug, and Cosmetic Act (Act) that requires premarket approval applications (PMA). You may, therefore, market your device pursuant to the general controls provisions of the Act. The general controls provisions of the Act do not require annual registration, listing of devices, labeling, and prohibitions against misbranding and adulteration. However, you must evaluate information related to contract liability and that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II or III (PMA), it may be subject to additional controls. Existing information on this device can be found in the Code of Federal Regulation. In addition, FDA may publish further announcements concerning this device on the [FDA website](#). For more information, please contact the [FDA Center for Devices and Radiological Health](#).

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

510(k) Premarket Notification

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

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 Correspondent	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
Regulation Number	880.6250
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
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

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

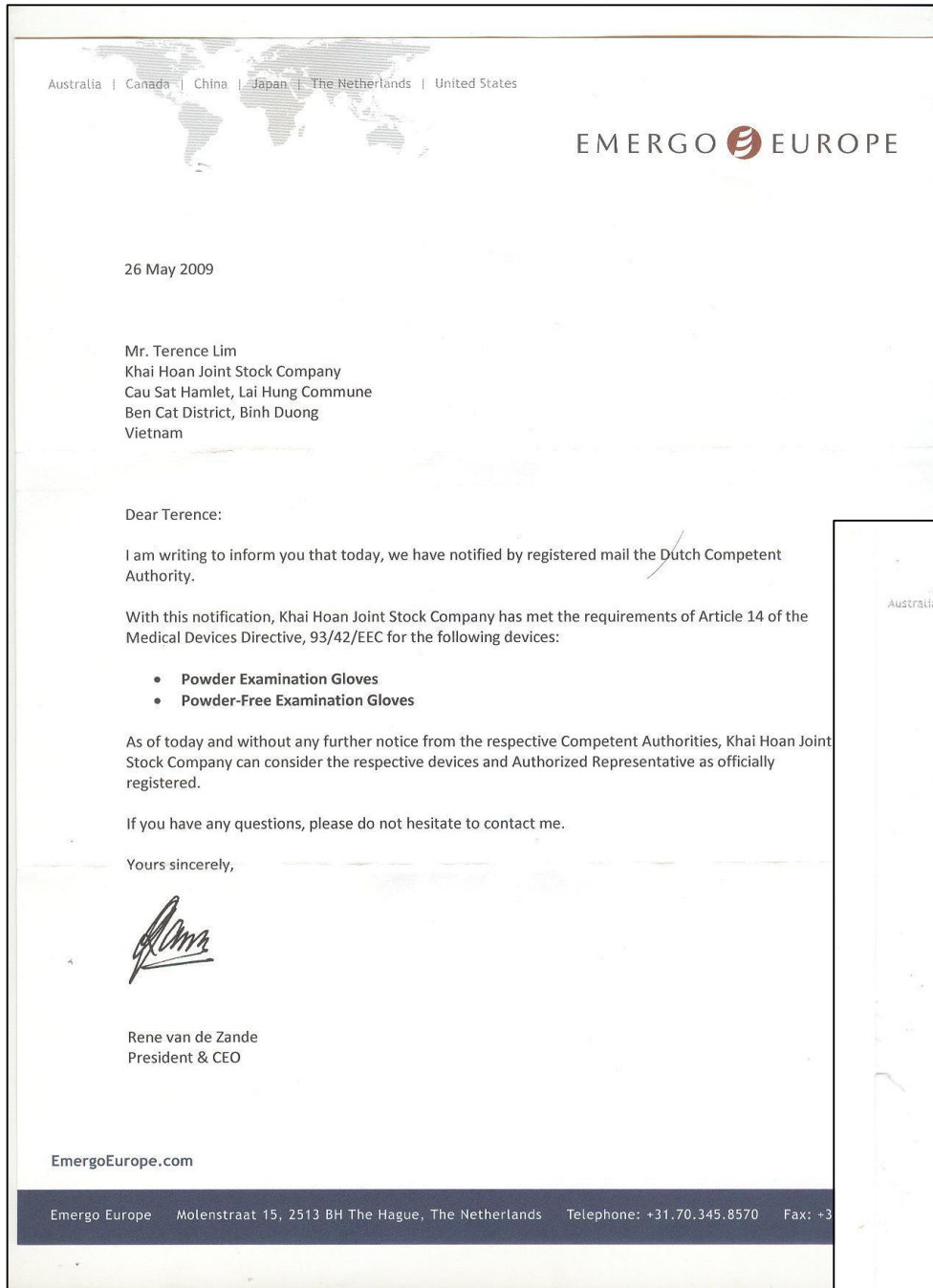
Combination Products
Advisory Committees
Science & Research
Regulatory Information

U.S. Department of Health & Human Services



<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

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



COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑 Certification EN ISO 13485:2016 / 22000:2005

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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.**

Stewart Brain

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

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

Effective Date:

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

Expiry Date:



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.



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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**

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



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**



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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.



COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑 Certification ISO 9001:2015



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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
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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

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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, Venkataram Arabolu

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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BSI, The MIRA Corporate Suites (A-2), Plot 1 and 2, Ishwar Nagar, Mathura Road, New Delhi 110 085.

A Member of the BSI Group of Companies



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



NI/CA01/001529
CE Marking



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

(Circular No. 28/2012/TT-BKHHCN dated December 12th 2012 and Circular No. 02/2017/TT-BKHHCN
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
Tel: (84-28) 3829 4274 Fax: (84-28) 3829 3012

Trang / page 1/1



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



NI/CA01/001529
CE Marking



QUATEST3



Free Sale's Certificate



Circulation Certificate

REGISTRATION FOR CIRCULATION OF MEDICAL DEVICE MANUFACTURING IN VIETNAM

베트남 의료 기기 제조허가증

BỘ Y TẾ

Hà Nội, ngày (date): 06/5/2011

Số (No) 15/2011/BYT-TB-CT

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 PHẨMHAS 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, KHPPSS
(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