COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

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

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

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

CE Marking · QUATEST3 · Free Sale's Certificate · Circulation Certificate

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

COVID-19
Vglove Non-sterile Powder-free Nitrile gloves

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

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

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 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 con
Register.

FDA 510K Cleared Medical Devices

FDA 510K

U.S. Department of Health & Human Services

U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

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

510(k) Premarket Notification

FDA Home > Medical Devices > Databases

CDRH SuperSearch

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

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 HAMLET, LAI HUNG COMMUNE, BEN CAT DISTRICT Binh Duong Province, VN
Applicant Contact	Pham N Thanh
Correspondent	KHAI HOAN JOINT STOCK COMPANY CAU SAT HAMLET, 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 | Kreyol Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies

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

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

CE Marking | QUATEST3 | Free Sale's Certificate | Circulation Certificate

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

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

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/dm^2 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 mis

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.

FDA 510K Cleared Medical Devices

FDA 510K

U.S. FOOD & DRUG ADMINISTRATION

Follow FDA | En Español

SEARCH

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

510(k) Premarket Notification

FDA Home > Medical Devices > Databases

CDRH SuperSearch

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

New Search — Back to Search Results

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	03/10/2012
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

Page Last Updated: 05/04/2020
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 | ภาษาไทย | English

Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies

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

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

CE Marking | QUATEST3 | Free Sale's Certificate | Circulation Certificate

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

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

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: +3

CE

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

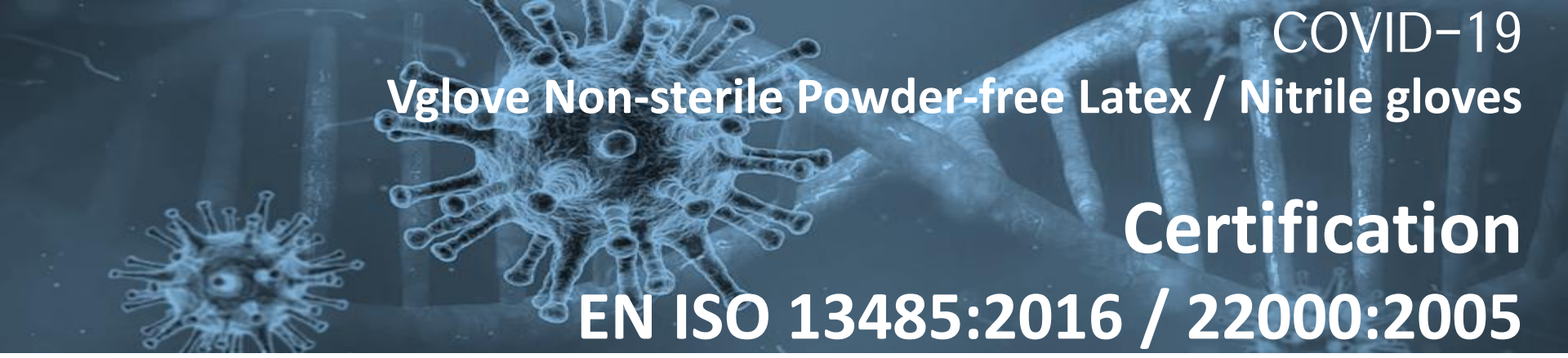
EmergoEurope.com

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

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

NL/CA01/601529 CE Marking | QUATEST3 | Free Sale's Certificate | Circulation Certificate

https://www.emergobyul.com/



COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

Certification

EN ISO 13485:2016 / 22000:2005

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 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** Effective Date
Latest Revision Date: **02/05/2018** Expiry Date: 1

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 telep
Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements
the organization. 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.

ISO 22000:2005

13485:2016

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**

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.™

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 telephone +84 (28) 38 200 066
Further clarifications regarding the scope of this certificate and the applicability of ISO 22000:2005 requirements may be obtained by consulting the organization. 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.

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

Certification ISO 9001:2015

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

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

Page: 1 of 1

...making excellence a habit™

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 telephone +84 (28) 38 200 066
Further clarifications regarding the scope of this certificate and the applicability of ISO 9001: 2015 requirements may be obtained by consulting the organization. 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.

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

Certification SA 8000

bsi.

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, Venkataram Arabolu

Original Registration Date: **19/11/2013**
Latest Revision Date: **11/11/2019**

Effective Date: **19/11/2019**
Expiry Date: **18/11/2022**

Page: 1 of 1

...making excellence a habit.™

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.bsi-global.com/Client Directory or telephone +91 11 2692 9000.
Further clarifications regarding the scope of this certificate and the applicability of SA 8000: 2014 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Social Accountability International and other stakeholders in the SA 8000 process only recognize SA 8000 certificates issued by qualified Certification Bodies granted accreditation by SAAS and do not recognize the validity of SA 8000 certificates issued by unaccredited organizations or organizations accredited by an entity other than SAAS. Stakeholders can confirm the validity of an accredited SA 8000 certificate at this website, www.saasaccreditation.org/certification.

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 Companies

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

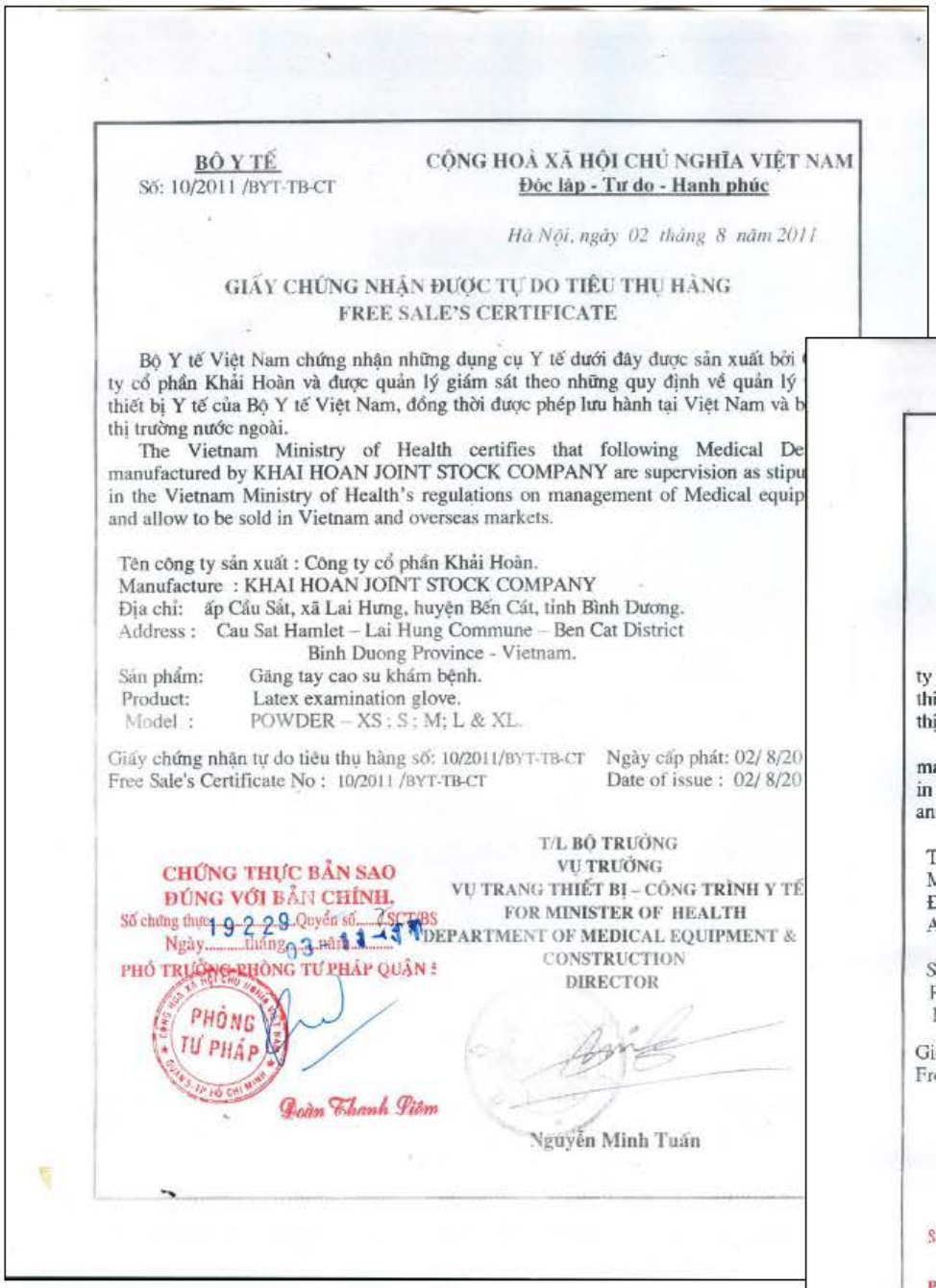
CE Marking | QUATEST3 | Free Sale's Certificate | Circulation Certificate

https://www.emergobyul.com/

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

Vietnam Ministry of Health certified



BỘ Y TẾ
Số: 10/2011 /BYT-TB-CT

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh phúc

Hà Nội, ngày 02 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
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.
Product: Latex examination glove.
Model : POWDER – XS ; S ; M; L & XL.

Giấy chứng nhận tự do tiêu thụ hàng số: 10/2011/BYT-TB-CT Ngày cấp phát: 02/ 8/20
Free Sale's Certificate No : 10/2011 /BYT-TB-CT Date of issue : 02/ 8/20

T/L BỘ TRƯỞNG
VỤ TRƯỞNG
VỤ TRANG THIẾT BỊ – CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL EQUIPMENT & CONSTRUCTION
DIRECTOR

CHỨNG THỰC BẢN SAO
ĐÚNG VỚI BẢN CHÍNH.
Số chứng thực 19229 Quyển số 7 SCT/BS
Ngày 03 tháng 11 năm 11
PHÓ TRƯỞNG PHÒNG TƯ PHÁP QUẬN 5

PHÒNG TƯ PHÁP

Đoàn Thanh Liêm

Nguyễn Minh Tuấn

BỘ Y TẾ
Số: 16/2011 /BYT-TB-CT

CỘNG HOÀ XÃ HỘI CHỦ NGHĨA VIỆT NAM
Độc lập - Tự do - Hạnh 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 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.
Product: Latex examination glove.
Model : POWDER FREE – XS ; S ; M; L & XL.

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
VỤ TRANG THIẾT BỊ – CÔNG TRÌNH Y TẾ
FOR MINISTER OF HEALTH
DEPARTMENT OF MEDICAL EQUIPMENT & CONSTRUCTION
DIRECTOR

CHỨNG THỰC BẢN SAO
ĐÚNG VỚI BẢN CHÍNH.
Số chứng thực 19243 Quyển số 7 SCT/BS
Ngày 03 tháng 11 năm 11
PHÓ TRƯỞNG PHÒNG TƯ PHÁP QUẬN 5

PHÒNG TƯ PHÁP

Đoàn Thanh Liêm

Nguyễn Minh Tuấn

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

CE XL/CAD1/001859 CL Marking · QUATEST3 · Free Sale's Certificate · Circulation Certificate

COVID-19

Vglove Non-sterile Powder-free Latex / Nitrile gloves

Vietnam QUATEST3

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

QUATEST3
ASTM D 3578-05

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

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

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

REGISTRATION FOR CIRCULATION OF MEDICAL DEVICE MANUFACTURING IN VIETNAM

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 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, 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