

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



ISO 9001:2008



ISO 13485:2003



ISO 22000:2005



FDA 510K



NL/CA01/601529  
CE Marking



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Free Sale's Certificate



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# 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 interstate commerce prior to May 28, 1976, the enactment of the Federal Food, Drug, and Cosmetic Act (Act) that requires approval application (PMA). You may, therefore, market your device under the general controls provisions of the Act. The general controls provisions of the Act require, among other things, 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 devices of this type can be found in the Code of Federal Regulations. In addition, FDA may publish further announcements concerning this device on the [FDA Register](#).

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

**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
Correspondent	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	<a href="#">Statement</a>
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 | Pycckий | 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

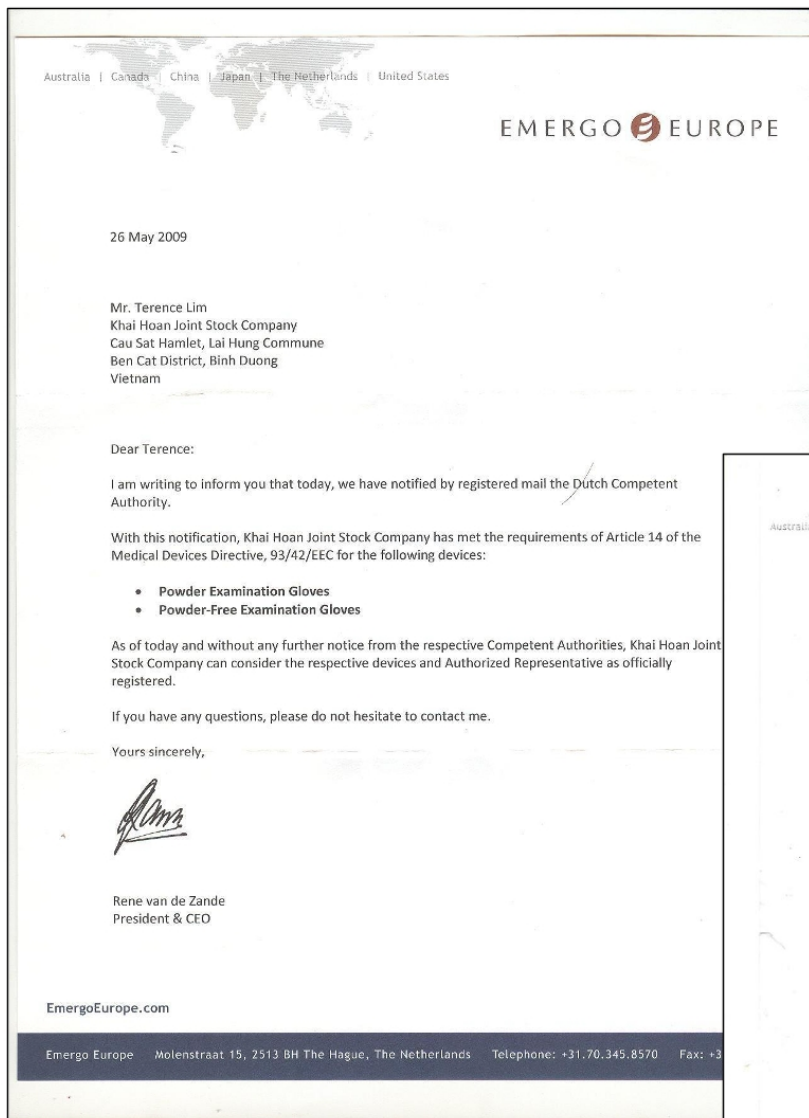


<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>





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



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



# COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves

## 코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

# Certification

## EN 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 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**

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



**bsi.**



## 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.  
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# COVID-19 Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비멸균 라텍스/니트릴 의료용 장갑

## Certification SA 8000

**bsi.**



## 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**

*(Handwritten signature)*



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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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](http://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



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COVID-19

# Vglove Non-sterile Powder-free Latex / Nitrile gloves

코로나 Vglove 비말균 라텍스/니트릴 의료용 장갑

## Vietnam Ministry of Health certified

### 베트남 보건부 의료기기 국내외 판매허가서

**BỘ Y TẾ** CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM  
Số: 10/2011 /BYT-TB-CT **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 Công 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 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  
Bình 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

**CHỨNG THỰC BẢN SAO ĐÚNG VỚI BẢN CHÍNH.**  
Số chứng thực: 19229...Quyển số: 2 SCT/BS  
Ngày: 03 tháng 03 năm 2011  
**PHÓ TRƯỞNG PHÒNG TỬ PHÁP QUẬN 5**

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

**Đoàn Thanh Liêm**  
Nguyễn Minh Tuấn

**BỘ Y TẾ** CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM  
Số: 16/2011 /BYT-TB-CT **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  
Bình 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

**CHỨNG THỰC BẢN SAO ĐÚNG VỚI BẢN CHÍNH.**  
Số chứng thực: 19243...Quyển số: 2 SCT/BS  
Ngày: 03 tháng 03 năm 2011  
**PHÓ TRƯỞNG PHÒNG TỬ PHÁP QUẬN 5**

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

**Đoàn Thanh Liêm**  
Nguyễn Minh Tuấn





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 KHAI 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 Bầu 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 12<sup>th</sup> 2012 and Circular No. 02/2017/TT-BKHCN dated March 31<sup>st</sup> 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 04<sup>th</sup>, 2019 to May 03<sup>rd</sup>, 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

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 Fax: (84-28) 3829 3012

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

