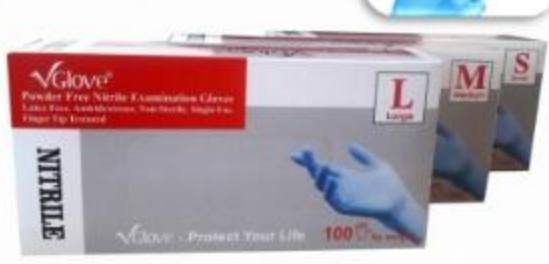
Nitrile Gloves

NITRILE GLOVES POWDER FREE



HACCP & GMP Food Safety Management

BSI ANAB ISO 9001:2015

ISO 13485 Medical Devices Quality Management

QUATEST3

ISO 22000 Food Safety System Certification

SL/CA01/601339
CE Certificate

FDA 510K Cleared Medical Devices

Free Sale's Certificate

SA8000:2014

Functional Benefits:

- Protection from unwanted and dangerous substances
- Beaded cuff ensures easy donning and prevent roll down
- Superior strength with better puncture resistance
- Full textured or Finger Tip textured enhances wet and dry grip
- Thinner gauge improves tactile sensitivity
- Custom design enhances comfort and fit
- Provide an alternative solution for individuals who are allergic to natural rubber latex

Product Specifications

Material	Synthetic Nitrile latex.
Type	Non-Sterile Powder-Free. Ambidextrous; Finger Tip Textured; Beaded Cuff; White or Coloured (Blue, Light Blue, ...)
Quality Standards	Conforms to ASTM D6319 Manufactured under ISO9001: 2008, ISO 13485:2003. ISO 22000:2005 Quality Management System. Manufactured from 100% nitrile (Acrylonitrile-Butadiene)
Gloves Size	Extra-small, Small, Medium, Large, Extra-large. Marked in the check box on the shipping carton with black ink.
Storage	Store in a dry and cool place, the temperature not higher than 38°C.
Shelf-fife	3 years from the date of manufacturing.

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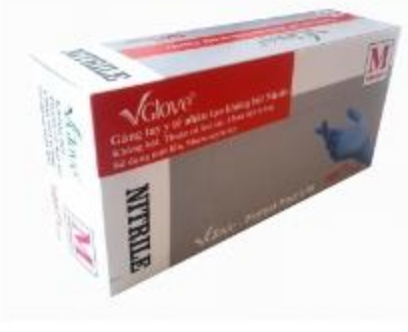
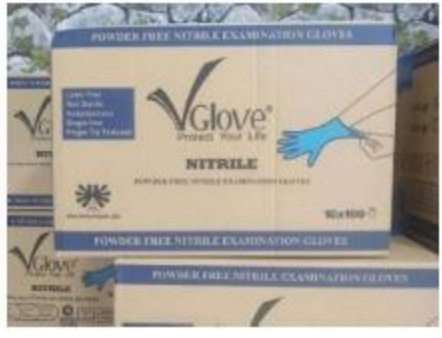
PHYSICAL DIMENSIONS

DIMENSIONS	Standards	
	VRG KHAI HOAN	ASTM D6319
Length (mm)	230 min	220 min (XS, S) 230 min (M, L, XL)
Width (mm)	75 ± 5 (XS) 85 ± 5 (S) 95 ± 5 (M) 105 ± 5 (L) 115 ± 5 (XL)	70 ± 10 (XS) 80 ± 10 (S) 95 ± 10 (M) 110 ± 10 (L) 120 ± 10 (XL)
Thickness- Single wall (mm)	Fingers : 0. 08 mm min Palm : 0.06 mm min	Fingers : 0.050 mm min Palm : 0.05 mm min

PHYSICAL PROPERTIES AND BIOCOMPATIBILITY

Tensile	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min Elongation at break (%) Before aging: 600% min After aging: 500% min	Tensile strength (MPA) Before aging: 14Mpa min After aging: 14Mpa min Elongation at break (%) Before aging: 500% min After aging: 400% min
Powder Content	2 mg/glove maximum	
Protein Content	Free Protein	





Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

CE

Australia | Canada | China | Japan | The Netherlands | United States

EMERGO EUROPE

26 May 2009

[redacted]

[redacted]

[redacted]

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,

[redacted]

[redacted]

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

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

FDA_1

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Mr. Lim

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[redacted]

Enclosure

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

GMP

bsi.

By Royal Charter

Certificate of Registration

GOOD MANUFACTURING PRACTICE – GMP

This is to certify that:

[redacted]

Holds Certificate Number: **BSIVN 1313/2019**

and operates a Good Manufacturing Pratice which complies with the requirements of GMP-HACCP (CAC/RCP 1-1969, Rev.4-2003) 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: [redacted]

Original Registration Date: **10/06/2019**
Latest Revision Date: **10/06/2019**

[redacted]

bsi.

[redacted]

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

ISO13485 : 2016

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

[redacted]

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.

For and on behalf of BSI:

[redacted]

Original Registration Date: **18/05/**[redacted]
Latest Revision Date: **02/05/2018**

[redacted]

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

ISO 9001 : 2015

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

[redacted]

Holds Certificate Number: **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:

[redacted]

Original Registration Date: **01/06/2**[redacted]
Latest Revision Date: **30/05/2018**

[redacted]

...making excellence a habit.

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

ISO 22000 : 2005

bsi.

By Royal Charter

Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2005

This is to certify that:

[redacted]

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

For and on behalf of BSI:

[redacted]

Original Registration Date: **09/10/2[redacted]**
Latest Revision Date: **14/07/2018**

[redacted]

bsi.

ANAB ACCREDITED MANAGEMENT SYSTEMS CERTIFICATION BODY

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification
Registration

QUATEST 3®

[redacted]

GIẤY CHỨNG NHẬN
CERTIFICATE

Số / N_o: 12-07
(KH1-CNL-2019)

Chứng nhận sản phẩm / *This is to certify that:*

[redacted] / **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)

[redacted]

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

QUATEST 3
ASTM D 3578-05

Trung tâm Kỹ thuật Tiêu chuẩn Đo lường Chất lượng 3
Quality Assurance and Testing Center 3

[redacted]

Nitrile Gloves

NITRILE GLOVES
POWDER FREE

Certification

SA 8000 : 2014

bsi.

By Royal Charter

Certificate of Registration

SOCIAL ACCOUNTABILITY SYSTEM - SA 8000:2014

This is to certify that:

[redacted]

Holds Certificate Number: **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:

[redacted]

Original Registration Date: **19/11/2[redacted]**
Latest Revision Date: **11/11/2019**

[redacted]

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

Nitrile Gloves

NITRILE GLOVES
POWDER FREE
丁晴无粉手套

- (100 pcs、50 pairs/BOX)
- Carton size：（34cm*25cm* 24cm）（ 100 Gloves/1 Box）
  （Carton/10 boxes）（6 kg/Carton）
- Assistance in shipping to the country, additional shipping costs are required

- **Origin: Vietnam** 产地：越南
- **Daily output: 20 million pieces / day**
- The goods are shipped without waiting and shipped in time

☐ **Document Required.**订购需要文件

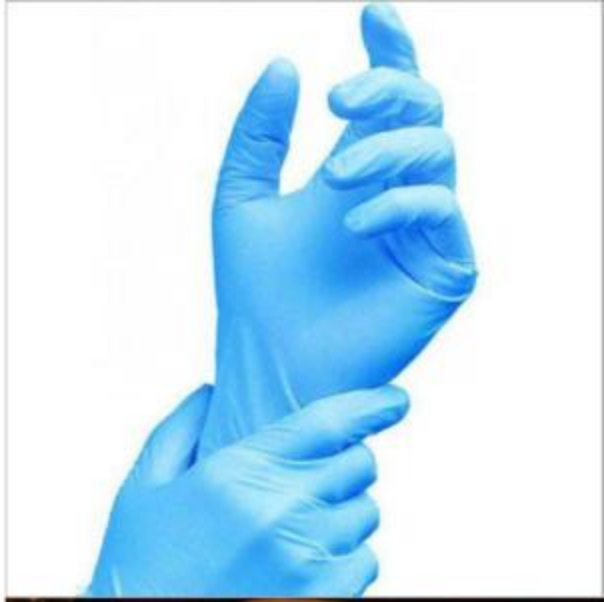
1. Letter of Intent Buyer's (LOI)
2. ICPO (Company form) 买家提供采购订单
3. Corporate Registration Certificate 买家提供企业登记证
4. Financial status documents (Proof of funds or Financial certificate or Bank account book Statement Latest month)财务状况文件（资金证明或财务证明书或银行账户结单最近一月）

☐ **Operating procedures** 购买流程

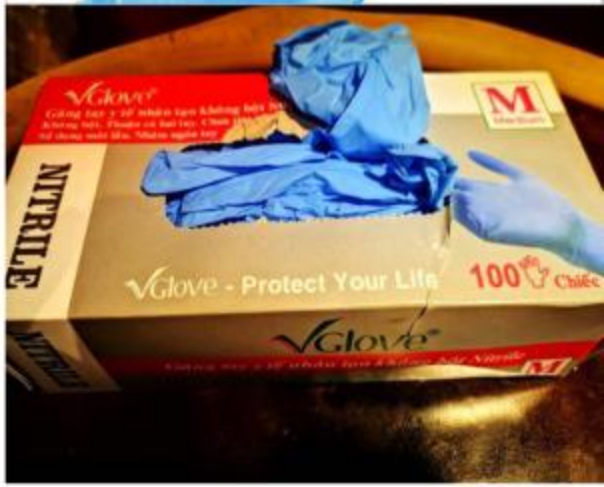
1. Buyers issue Letter of Intent and documents 1-4 to the company.买方1-4号文件
2. Seller checks the completeness of various documents. And confirm within 2 working days卖方检查各种文件的完整性，并在2个工作日内确认。
3. Buyer inspecting and editing the contract And confirm back 买方检查和编辑贸易合同并确认
4. Schedule a contract or sign an online contract immediately 安排合同或立即签订在线合同
5. Buyers pay according to the agreement. And the selected format 根据合同付款出货

Nitrile Powederd free gloves 丁晴无粉手套

- Assistance in shipping to the country, additional shipping costs are required可协助办理货运至国家，运费另计



- Origin: Vietnam 产地：越南
- Daily output: 20 million pieces / day 日产量：2,000万/天
- The goods are shipped without waiting and shipped in time货品订购及时出货，免等待



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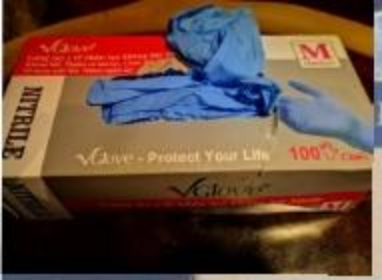

POWDER FREE NITRILE EXAMINATION GLOVES

Latex Free
Non Sterile
Ambidextrous
Single-Use
Finger Tip Textured

VGlove®
Protect Your Life

NITRILE

POWDER FREE NITRILE EXAMINATION GLOVES

VRG KHAI HOAN JSC

10x100

POWDER FREE NITRILE EXAMINATION GLOVES

VGlove®
Protect Your Life

NITRILE

găng tay y tế nhân tạo không bột Nitrile

POWDER FREE NITRILE EXAMINATION GLOVES

FDA 510K

CE Marking

ISO SA8000

QUATEST3

Free Sale's Certificate

Circulation Certificate