MEDICAL GLOVE

Nitrile Glove

(Powdered/ Powder Free)

Vglove

Vglove – Nitrile glove

Power Free

Glove Nitrile it's protect for Doctor when treatment for Patients. Elastic Glove it work well on different weather.

Product information

Vglove – Nitrile glove

Power Free

PRODUCT IMAGES

Blue

Front

White

Back

CARTON PACKING

SPECIFICATION CARTON

Size: 360mmx260mmx240mm
Weight: 4kg/carton
1 Carton : 10 boxes
1 boxes : 100 pieces

Product information

Vglove – Nitrile glove

Power Free

PRODUCT IMAGES

Product information

Vglove – Nitrile glove

Power Free

MATERIAL	Artificial Nitrile rubber
Kind	Do not pasteurized powder
	Used for both hands, rough fingertip surface, wrist trim, white and blue
Quality standards	Accord with ASTM D6319 standards
	Manufactured under ISO 9001: 2008, ISO 13485:2003, IS 22000:2005. quality management system.
	Produced from 100% nitrile (Acrylonitrile-Butadiene)
Glover size	Extra-small, Small, Medium, Large, Extra-large.
	Size is marked on the container with black ink
Preservation	Store in a cool, dry place, temperature not higher than 30 degrees Celsius.
Expiry date	3 years from the date of manufacture

SIZE	STANDARD	
	VRG KHAI HOAN	ASTM D6319
Length (mm)	230 min	220 min (XS, S)
		230 min (M, L, XL)
Width (mm)	75 ± 5 (XS)	70 ± 10 (XS)
	85 ± 5 (S)	80 ± 10 (S)
	95 ± 5 (M)	95 ± 10 (M)
	105 ± 5 (L)	110 ± 10 (L)
	115 ± 5 (XL)	120 ± 10 (XL)
Thickness (mm)	Finger: 0. 08 mm min	Finger: 0.05 mm min
	Palm: 0.06 mm min	Palm: 0.05 mm min

Product information

Vglove – Nitrile glove

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PHYSICAL AND CHEMICAL INDICATORS

Tensile	Tensile strength (MPA) Before aging: 18Mpa min After aging: 20Mpa min	Tensile strength (MPA) Before aging: 14Mpa min After aging: 14Mpa min
	Elongation at break (%) Before aging: 600% min After aging: 500% min	Elongation at break (%) Before aging: 500% min After aging: 400% min
Powder content	Maximum 2 mg /glove	
Protein content	No protein	

ISO 13485 Medical Devices Quality Management

HACCP & GMP Food Safety Management

ISO 22000 Food Safety System Certification

ISO 9001 Quality Management

Free Sale's Certificate

ISO 9001:2015

QUATEST3

SA8000:2014

FDA 510K Cleared Medical Devices

CE Certificate

Vglove Certificate

UKcert
Certification & Inspection

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

Certificate No.: CE-32287

Manufacturer

Name : **Khai Haon Joint Stock Company**

Address : **Cau Sat Hamlet, Lai Hung Commune, Ben Cat District, Binh Duong, Vietnam**

Products : **Powder Examination Gloves & Powder-Free Examination Gloves**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Council Directive on Medical Devices 93/42/EEC as Amended 2007/47/EC.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of initial registration	12th May 2020
Date of this Certificate	12th May 2020
Certificate Expiry	11th May 2021
Recertification Due (subject to the company maintaining its system to the required standard)	11th May 2023

Authorised Signatory

UK Certification & Inspection LTD

This certificate is the property of UK Certification & Inspection Limited and shall be returned immediately on request.
71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom
Website:- www.ukcertifications.org.uk, email:- info@ukcertifications.org.uk
Company No. 11847851

Vglove Certificate

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, [redacted] 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: +31.70.346.7299

Vglove Certificate

Australia | Canada | Chile | 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

Vglove Certificate

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 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.

Vglove Certificate

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,

for Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Vglove Certificate

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By Royal Charter

Giấy Chứng Nhận

THỰC HÀNH SẢN XUẤT TỐT – GMP

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng, Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **BSIVN 1313/2019**

và thực hiện Thực Hành Sản Xuất Tốt phù hợp với các yêu cầu của GMP-HACCP (CAC/RCP 1-1969, Rev.4-2003) cho phạm vi:

Sản xuất và phân phối:
- Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột.
- Găng tay nitrile y tế không tiệt trùng, không bột.

Đại diện cho tập đoàn BSI: *Tổng Giám đốc BSI Việt Nam, Ông Lê Duyên Anh*

Ngày đăng ký đầu tiên: **10/06/2019**
Ngày hiệu lực: **10/06/2019**
Ngày sửa đổi sau cùng: **10/06/2019**
Ngày hết hiệu lực: **09/06/2022**

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Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG - ISO 9001:2015

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **FM 548618**

và thực hiện Hệ Thống Quản Lý Chất Lượng phù hợp với các yêu cầu của ISO 9001:2015 cho phạm vi:

Sản xuất và phân phối:
Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột;
Găng tay nitrile y tế không tiệt trùng không bột.

Đại diện cho tập đoàn BSI: Chris Cheung, Phụ Trách Sự Tuân Thủ & Rủi Ro Châu Á Thái Bình Dương

Ngày đăng ký đầu tiên: **01/06/2009**
Ngày sửa đổi sau cùng: **30/05/2018**

Ngày hiệu lực: **01/06/2018**
Ngày hết hiệu lực: **31/05/2021**

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Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG - ISO 9001:2015

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **FM 548618**

và thực hiện Hệ Thống Quản Lý Chất Lượng phù hợp với các yêu cầu của ISO 9001:2015 cho phạm vi:

Sản xuất và phân phối:
Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột;
Găng tay nitrile y tế không tiệt trùng không bột.

Đại diện cho tập đoàn BSI: Chris Cheung, Phụ Trách Sự Tuân Thủ & Rủi Ro Châu Á Thái Bình Dương

Ngày đăng ký đầu tiên: **01/06/2009**
Ngày sửa đổi sau cùng: **30/05/2018**

Ngày hiệu lực: **01/06/2018**
Ngày hết hiệu lực: **31/05/2021**

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Giấy Chứng Nhận

HỆ THỐNG QUẢN LÝ CHẤT LƯỢNG - ISO 13485:2016 & EN ISO 13485:2016

Xác nhận rằng:

CÔNG TY CỔ PHẦN VRG KHẢI HOÀN
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **MD 548620**

và thực hiện Hệ Thống Quản Lý Chất Lượng phù hợp với các yêu cầu của ISO 13485:2016 & EN ISO 13485:2016 cho phạm vi:

Sản xuất và phân phối:
Găng tay cao su thiên nhiên y tế không tiệt trùng có bột và không bột;
Găng tay nitrile y tế không tiệt trùng không bột.

Đại diện cho tập đoàn BSI: Stewart Brain, Giám Đốc Tuân Thủ & Rủi Ro – Thiết Bị Y Tế

Ngày đăng ký đầu tiên: **18/05/2009**
Ngày sửa đổi sau cùng: **02/05/2018**
Ngày hiệu lực: **18/05/2018**
Ngày hết hiệu lực: **17/05/2021**

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By Royal Charter

Giấy Chứng Nhận

HỆ THỐNG TRÁCH NHIỆM XÃ HỘI - SA 8000:2014

Xác nhận rằng: **CÔNG TY CỔ PHẦN VRG KHẢI HOÀN**
Ấp Cầu Sắt,
Xã Lai Hưng,
Huyện Bàu Bàng,
Tỉnh Bình Dương,
Việt Nam

Giữ giấy chứng nhận số: **SA 598117**

và thực hiện Hệ thống Trách Nhiệm Xã Hội phù hợp với các yêu cầu của Tiêu Chuẩn Trách Nhiệm Xã Hội SA 8000:2014 cho phạm vi:

Sản xuất và phân phối găng tay y tế cao su có bột và không bột, găng tay cao su nitrile bao gồm các quá trình tiếp nhận nguyên vật liệu latex/ nitrile, phối trộn, tạo đông, lưu hóa, tách chiết, nhúng bột bắp/chlorine, sấy khô, kiểm tra và đóng gói.

Các quá trình gia công ngoài: Không.
Các quá trình hợp đồng ngoài: Không.

Đại diện cho tập đoàn BSI: *Tổng Giám Đốc BSI Ấn Độ, Venkataram Arabolu*

Ngày đăng ký đầu tiên: **19/11/2013**
Ngày sửa đổi sau cùng: **11/11/2019**

Ngày hiệu lực: **19/11/2019**
Ngày hết hiệu lực: **18/11/2022**

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Issued to:

VRG Khai Hoan JSC
Cau Sat Hamlet
Lai Hung Commune
Bau Bang District
Binh Duong Province
Vietnam

Notified Body: 2777

SATRA customer number: P1434

EU Type-Examination Certificate

Certificate number: 2777/11582-01/E00-00

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

PFNBR

Description:

Non-sterile powder free nitrile examination gloves

Sizes:

XS/6, S/7, M/8, L/9, XL/10

Classification:

EN ISO 374-1: 2016 / Type B	**Level**	**EN ISO 374-4:2013 % Degradation**
40% Sodium hydroxide (K)	6	-13.2
30% Hydrogen peroxide (P)	4	5.3
37% Formaldehyde (T)	6	4.6
EN ISO 374-5: 2016		
Protection against Bacteria and fungi	Pass	
Protection against viruses	Pass	

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0225034/1420/2, SPC0225034/1420/SMcD/B, SPC0244727/1615, CHM0248775/1632/SMcD, CHM0272778/1827/LH, CHM0276386/1840/JH, SPC0244727/1615, SPC0273658/1830, CHM0273594/1830/LH/A, CHM0273594/1830/LH/B, CHM0273594/1830/LH/C
TUV: 7191169844-CHM17-01-RC

Signed on behalf of SATRA: Tara Saunders Austin Simmons

Date first issued: 23/11/2018
Date of issue: 23/11/2018

Expiry date: 23/11/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

The certificate holder is licensed to mark the products detailed within this certificate in accordance with Annex V (Module B) of the Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment once you have drawn up an EU declaration of product conformity. Please note:

1. Where the product is classified as category III then CE Marking of production is reliant on current compliance with Regulation 2016/425 module C2 or Module D. (Except that specifically produced to fit an individual user).
2. Full details of the certification and product are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturers technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate.
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state government.
8. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
9. SATRA Technology reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425.