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:

Vietnam

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: 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**

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Nitrile Gloves

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Certification

ISO 22000：2005

bsi.

By Royal Charter

Certificate of Registration

FOOD SAFETY MANAGEMENT SYSTEM - ISO 22000:2005

This is to certify that:

Vietnam

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: 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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健康国际 HEALTHY LIFE

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Expiry Date: **31/05/2021**

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Registration

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*:

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

QUATEST 3
ASTM D 3578-05

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

TRUNG TÂM KỸ THUẬT TIÊU CHUẨN ĐO LƯỜNG CHẤT LƯỢNG 3

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 *Tel: (84-28) 3829 4274* *Fax: (84-28) 3829 3012*
49 Pasteur, District 1, Ho Chi Minh City *Tel: (84-28) 3829 4274* *Fax: (84-28) 3829 3012*

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ISO 22000：2005

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Certificate of Registration

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This is to certify that:

Vietnam

Holds Certificate Number: **FSMS 552546**

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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**

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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*:

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

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Phương thức 5 / *Scheme 5*

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The certificate remains valid from May 04th, 2019 to May 03rd, 2022

QUATEST 3
ASTM D 3578-05

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PHÓ GIÁM ĐỐC / VICE DIRECTOR

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POWDER FREE

Certification

SA 8000 : 2014

bsi.

By Royal Charter

Certificate of Registration

SOCIAL ACCOUNTABILITY SYSTEM - SA 8000:2014

This is to certify that:

Vietnam

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: 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**

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Certification

CE

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

EMERGO EUROPE

26 May 2009

Mr. Terence Lim

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

Please be advised that FDA's issuance of a substantial equivalence determination does n mean that FDA has made a determination that your device complies with other requirem 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: registrati 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 82 and if applicable, the electronic product radiation control provisions (Sections 531-542 o 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 f the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Alsc 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' Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from th 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 Hospit
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure