



**NITRILE GLOVES  
POWDER FREE**

**Certification**

**ISO 9001 : 2015**



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**

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  
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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:

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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Nitrile Gloves

**NITRILE GLOVES  
POWDER FREE**

**Certification  
Registration**



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:

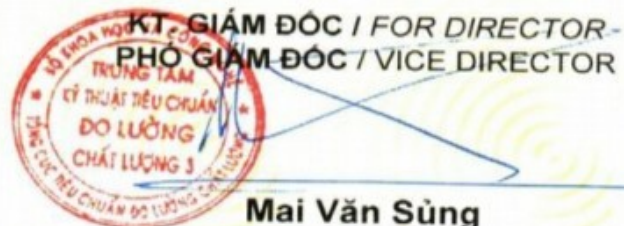
**Phương thức 5 / Scheme 5**

(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 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



**Mai Văn Sùng**

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  
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Fax: (84-28) 3829 3012

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POWDER FREE

Certification

ISO 22000 : 2005

bsi.



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# 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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Nitrile Gloves

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POWDER FREE**

**Certification  
Registration**



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:

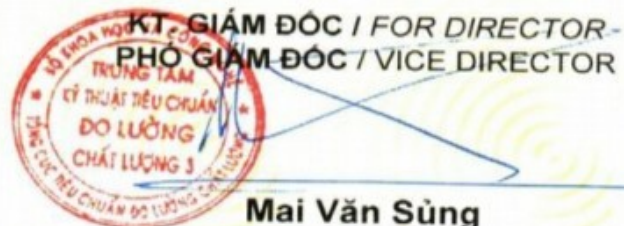
**Phương thức 5 / Scheme 5**

(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 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



**Mai Văn Sùng**

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NITRILE GLOVES  
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SA 8000 : 2014



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**

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 健康国际 HEALTHY LIFE

Nitrile Gloves

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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



FDA\_

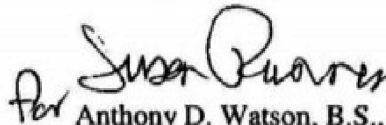
Page 2 -- Mr. Lim

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,



for 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