



THƯ XÁC NHẬN

Ngày: 30/08/ 2017

Kính gửi Quý khách hàng:

Công ty TNHH Bureau Veritas Certification Việt Nam xác nhận đã thực hiện việc đánh giá theo tiêu chuẩn ISO 13485:2003 tại Quý công ty theo chi tiết

- Tên công ty: **CÔNG TY CỔ PHẦN THIẾT BỊ Y TẾ HỒNG THIỆN MỸ.**
- Địa chỉ:
VP chính: 725/2 Trường Chinh, Phường Tây Thạnh, Quận Tân Phú, Tp. Hồ Chí Minh, Việt Nam
Chi nhánh 1: 436A/119 Đường 3/2, Phường 12, Quận 10, Hồ Chí Minh, Việt Nam
Chi nhánh 2: 42/4 Đường Bông Sao, Phường 5, Quận 8, Hồ Chí Minh, Việt Nam
- Tiêu chuẩn: ISO 13485: 2003
- Phạm vi: Sản xuất và kinh doanh ống nghiệm polymer sử dụng cho chuẩn đoán y tế.

Thu mua, kinh doanh và cung cấp các bộ dụng cụ chẩn đoán xét nghiệm và các phụ kiện kèm theo.

- Ngày đánh giá: 10-12/07/ 2017
- Loại hình đánh giá: Tái chứng nhận

Các điểm không phù hợp đã được đóng theo Quy định. Hồ sơ đánh giá hiện đang trong quá trình phê duyệt để cấp Giấy Chứng Nhận.

Trân trọng,

Bureau Veritas Certification Vietnam

Tạnh Tuấn Dũng
Tổng Giám đốc

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Tel: + 84 (0)710 3734 476
Fax: + 84 (0)710 3734 486

BUREAU VERITAS
Certification



Certification

Awarded to

Hong Thien My Medical Equipment Joint Stock Company

725/2 Truong Chinh Street, Tay Thanh Ward, Tan Phu District,
Ho Chi Minh City, Vietnam

This is a multi-site certificate, additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification certify that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below.

STANDARD

ISO 13485:2003

SCOPE OF SUPPLY

**Manufacture and sales of polymeric test tubes for in vitro diagnostic use.
Procurement, sales and supply of in vitro diagnostic kits and accessories.**

Original approval date: 01-09-2014

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: 31-08-2017

To check the validity of this certificate please call: (+45) 77 311 000.

Further clarification regarding the scope of this certificate and the applicability of the system requirements may be obtained by consulting the organisation

Certificate Number: DNKFRC98393A

Date: 23-09-2014

Certification office: Bureau Veritas Certification Denmark A/S
Oldenborggade 1B, 7000 Fredencia, Denmark
E-mail: medicaldkmail@dk.bureauveritas.com
Managing office: Unit 4.4A, 4th Floor-Etown building, 364 Cong Hoa Street, Tan Binh District, Ho Chi Minh City, Vietnam

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SYSTEM Reg.nr. 5005

BUREAU VERITAS
Certification



Certification

Awarded to

Hong Thien My Medical Equipment Joint Stock Company

Bureau Veritas Certification has issued this appendix to the certificate of approval of the above organisation.

SCOPE OF CERTIFICATION

Head Office:

Manufacture and sales of polymeric test tubes for in vitro diagnostic use.
Procurement, sales and supply of in vitro diagnostic kits and accessories.

Sites:	Address:	Scope:
Hong Thien My Medical Equipment Joint Stock Company	436A/119 Street 3/2, Ward 12, District 10, Ho Chi Minh City, Vietnam	Sales of polymeric, test tubes for in vitro diagnostic use. Procurement, sales and supply of in vitro diagnostic kits and accessories.
Hong Thien My Medical Equipment Joint Stock Company	42/4 Bong Sao Street, Ward 5, District 8, Ho Chi Minh City, Vietnam	Manufacture of polymeric, test tubes for in vitro diagnostic use.

Certificate Number: DNKFRC 98393A-1 Date: 23-09-2014

Certification office: Bureau Veritas Certification Denmark A/S,
Oldenborggade 1B, 7000 Fredenicia, Denmark
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Managing office:

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DANAK
SYSTEM Reg nr. 5005