



Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ  
*Embassy of the S.R. of Vietnam in the United States of America*

**CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ**  
**CONSULAR AUTHENTICATION**

1. Quốc gia  
*Country*

Việt Nam  
*Vietnam*

**Giấy tờ, tài liệu này**  
***This public document***

2. do Ông/Bà  
*has been signed by*

**Marco Rubio** ký

3. với chức danh:  
*acting in the capacity of*

**Bộ trưởng Ngoại giao**  
*Secretary of State*

4. và con dấu của  
*bears the seal/stamp of*

**Bộ Ngoại giao**  
*Department of State*

**được chứng nhận/hợp pháp hóa lãnh sự**  
***Certified***

5. tại Washington D.C., Hoa Kỳ  
*at Washington D.C.*

6. Ngày 04/09/2025  
*On the (dd/mm/yyyy)*

7. Cơ quan cấp: Đại sứ quán nước CHXHCN Việt Nam tại Hoa Kỳ  
*By the Embassy of the S.R. of Vietnam in the United States of America*

8. Số/No. **036-09/2025-HPH**

**TL. Đại sứ/For the Ambassador**  
**Tham tán/Counsellor**



**PHẠM TRẦN THANH THẢO**

9. Ghi chú: (i) Tem này không chứng nhận về nội dung và hình thức của giấy tờ, tài liệu/ *This certificate does not certify the content or the form of the document for which it was issued;* (ii) Tem chỉ có giá trị sử dụng tại Việt Nam/ *This certificate is valid for use in Viet Nam only.*

# Hợp chúng quốc Hoa Kỳ

## BỘ NGOẠI GIAO

### Hân hạnh kính gửi những người có liên quan:

Tôi xin chứng nhận rằng văn bản đính kèm theo đây được đóng con dấu của Bộ Y tế và Dịch vụ Nhân sinh, Hợp chúng quốc Hoa Kỳ và rằng con dấu đó có hiệu lực và được tin tưởng hoàn toàn.

*\*Bộ Ngoại giao không chịu trách nhiệm về các nội dung trong văn bản đính kèm.  
Chứng nhận này không có giá trị nếu bị tháo rời hay sửa đổi theo bất kỳ cách nào*

Để chứng thực, tôi, Marco Rubio, Bộ trưởng Ngoại giao, đã cho phép đóng dấu của Bộ Ngoại giao và tên của mình được ký bởi Phó Hợp pháp viên của Bộ trên, tại Thành phố Washington, District of Columbia ngày 21 tháng Tám, năm 2025.

(*đã ký và đóng dấu*)

Marco Rubio

Bộ trưởng Bộ Ngoại giao  
Phó Hợp pháp viên,  
Bộ Ngoại giao

*Chứng thực bà Khuất Duy Lê Minh, Tham tán, Đại sứ quán nước CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi.*

*Tôi, Khuất Duy Lê Minh, Tham tán, Đại sứ quán nước CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, cam đoan đã dịch chính xác văn bản này từ tiếng Anh sang tiếng Việt.*

Ngày 04 tháng 09 năm 2025

TL. Đại sứ  
Tham tán



Phạm Trần Thanh Thảo

Ngày 04 tháng 09 năm 2025

Người dịch

Khuất Duy Lê Minh

# United States of America



## DEPARTMENT OF STATE

*To all to whom these presents shall come, Greetings:*

I Certify That the document hereunto annexed is under the Seal of the Department of Health and Human Services, United States of America, and that such Seal is entitled to full faith and credit.\*

*\*For the contents of the annexed document, the Department assumes no responsibility  
This certificate is not valid if it is removed or altered in any way whatsoever*

In testimony whereof, I, Marco Rubio, Secretary of State, have hereunto caused the seal of the Department of State to be affixed and my name subscribed by the Assistant Authentication Officer, of the said Department, at the city of Washington, in the District of Columbia, this twenty-first day of August, 2025.

Marco Rubio  
Secretary of State

By Zm Daley  
Assistant Authentication Officer,  
Department of State

*Issued pursuant to CHXIV, State of  
Sept. 15, 1789, 1 Stat. 68-69; 22  
USC 2657; 22USC 2651a; 5 USC  
301; 28 USC 1733 et. seq.; 8 USC  
1443(f); RULE 44 Federal Rules of  
Civil Procedure.*

**Certificate No. 10668-7-2025-25**

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(Three Pages)

**Name of Manufacturer/Distributor, Address**

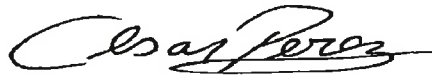
See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,



CDR Cesar A. Perez, PhD, Director  
DRP2: Division of Establishment Support  
Office of Regulatory Programs  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from July 22, 2025 to July 21, 2027.**



To verify the authenticity of the information on this certificate, you may scan the QR code or visit [www.access.fda.gov/fecv/CDRH](http://www.access.fda.gov/fecv/CDRH).

Certificate No. 10668-7-2025-25

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY  
17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Contract Manufacturer**

BENCHMARK ELECTRONICS, INC.  
4065 THEURER BLVD.  
WINONA, MN  
USA 55987

**Contract Manufacturer**

Measurement Specialties Chengdu  
No. 368 Wulian 1st Road  
Huangjia Street, Shuangliu District  
Chengdu, Sichuan  
CHINA 610200

**Contract Manufacturer**

SUPERCOMAL MEDICAL PRODUCTS, SDN BHD  
LOT 171, JALAN PKNK 3/8, KAWASAN  
PERUSAHAAN, SUNGAI PETANI  
SUNGAI PETANI, Kedah  
MALAYSIA 08000

**Contract Manufacturer**

Amphenol Medical Technologies (Dongguan) Co., Ltd.  
No.2, Xihu Industrial Park  
Qiaolong Road, Dengwu Village, Qiaotou  
Dongguan, Guangdong  
CHINA 523533

---END OF MANUFACTURER/DISTRIBUTOR LIST---



Certificate No. 10668-7-2025-25

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 3

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY  
17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Name of Product(s)**

Hemodynamic Monitoring Equipment  
64EKD, 64EKHH, 64EKM, 64EKMN, 64EKSM2  
64EKSM3, 70AN, 70AND, 70AND4, 70ANH  
70ANHHS, 70ANH, 70ANM4, 70ANN, 70ANN2, 70ANNK  
70ANSS, 9850A, OM2, OM2E  
HEMRLSTD1000, HEMBAT10, HEMOXCR1000, EVBB1, EVMB1, EVPB1, EVRS, EVS1

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY  
17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Contract Manufacturer**

BENCHMARK ELECTRONICS, INC.  
4065 THEURER BLVD.  
WINONA, MN  
USA 55987

**Name of Product(s)**

Vigileo Monitor and Accessories  
APCO9, MHAADPLT, MHAND, MHANM5, MHAPLMNT  
MHM1, MHM1E, MHM1R (Refurbished), MHM1ER (Refurbished)

Vigilance II Continuous Cardiac Output/Oximetry/Volumetric Monitor and Accessories  
(Vigilance II Monitor)

VIG2, VIG2AP, VIG2APK, VIG2E, VIG2S, VIG2SM  
VIG2ER (Refurbished), VIG2R (Refurbished)

EV1000 Clinical Platform  
EV1000A, EV1000DB, EV1000M, EVEC1, EVMB1  
EVFTCL, EVECL, EVPSA110, EVPSA110L, EVPSB220

EV1000 Clinical Platform NI  
EV1000CVR, EV1000M, EV1000NI  
EVEC1, EVEC12FT, EVEC3FT, EVECL, EVHRS, EVHRSBP, EVNIDBAC  
EVNIPCL12, EVNIPCL3, EVNIUPG, EVPMP  
PC2B, PC2CCC, PC2K, PCCVR

HemoSphere Advanced Monitoring Platform  
HEM1, HEMOXSC100, HEMSGM10, HEMEXPM10, HEMLPWCD1000, HEMLTECHM10, HEMPSC100  
HEMTOM10, HEMFSM10, HEMCSM10, HEMPC, HEMPC2K, HEMVITA1, HEMVWM1, HEMVTOM1  
HEMVEXPM1, HEMVLTECHM1

FloTrac Pressure Cable-BeneVision (compatible with BeneVision monitor)  
PSCOEM100MR  
FloTrac Pressure Cable-Philips (compatible with Philips monitor)  
PSCOEM100PH



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**Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 3**

HemoSphere Alta Advanced Monitoring Platform  
ALTACR1, ALTASR1, ALTAALL1

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY  
17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Contract Manufacturer**

Measurement Specialties Chengdu  
No. 368 Wulian 1st Road  
Huangjia Street, Shuangliu District  
Chengdu, Sichuan  
CHINA 610200

**Name of Product(s)**

Fore-Sight Elite Sensors  
FESL - Fore-Sight Elite Large Sensor  
FESM- Fore-Sight Elite Medium Sensor  
FESS - Fore-Sight Elite Small Sensor  
FESNS - Fore-Sight Elite Non-Adhesive Small Sensor

ForeSight Sensors

FESL - ForeSight Large Sensor  
FESM- ForeSight Jr Medium Sensor  
FESS - ForeSight Jr Small Sensor  
FESNS - ForeSight Jr Non-Adhesive Small Sensor  
FESLIQ - ForeSight IQ Large Sensor

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY  
17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Contract Manufacturer**

SUPERCOMAL MEDICAL PRODUCTS, SDN BHD  
LOT 171, JALAN PKNK 3/8, KAWASAN  
PERUSAHAAN, SUNGAI PETANI  
SUNGAI PETANI, Kedah  
MALAYSIA 08000

**Name of Product(s)**

Hemodynamic Monitoring Equipment  
64EKGE1, 64EKH, 64EKSM, 64EKMM, 70ANH, 70ANHS, 70ANM5, 70ANM6, 70ANM7, 70ANS, 70CC2  
COM2-CC, EVPSB220L, EVVTC1, EVFTC1, EVPMAC, EVPSB110, EVPSB110L

HemoSphere Alta - Monitor Pressure Cable  
HEMAPSC200  
Patient CCO Cable - HemoSphere Alta Advanced Monitoring Platform  
HEMA70CC2

**Name of Manufacturer**

**Legal Manufacturer**

BECTON, DICKINSON AND COMPANY



Certificate No. 10668-7-2025-25

Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 3

17200 Laguna Canyon Rd  
Irvine, CA  
USA 92618

**Contract Manufacturer**

Amphenol Medical Technologies (Dongguan) Co., Ltd.  
No.2, Xinhu Industrial Park  
Qiaolong Road, Dengwu Village, Qiaotou  
Dongguan, Guangdong  
CHINA 523533

**Name of Product(s)**

Hemodynamic Monitoring Equipment  
64EKBB, 64EKD2, 64EKLL, 64EKNK1, 64EKGE2, 70AND2, 70AND3, HEMDPT1000  
Acumen AFM Cable  
AAFMC  
Acumen AFM Cable-HemoSphere Alta Monitor  
HEMAFM100

-----END OF PRODUCT LIST-----

