

United States of America



DEPARTMENT OF STATE


To all to whom these presents shall come, Greetings:

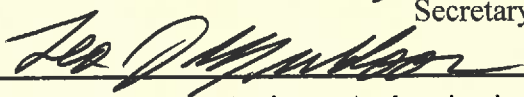
I Certify, That the document hereunto annexed is under the Seal of the Department of Health and Human Services, United States of America, and that such Seal is entitled to full faith and credit.*

**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, Michael R. Pompeo, 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 seventeenth day of October, 2019.

*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.*


Secretary of State

By 
Assistant Authentication Officer,
Department of State



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 Việt Nam
Country

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) Michael R. Pompeo ký
has been signed by

3. với chức danh Bộ trưởng ngoại giao
acting in the capacity of

4. và con dấu của Bộ Ngoại giao
bears the seal/stamp of

..... Hợp chủng quốc Hoa Kỳ.....

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Washington D.C 6. ngày 22 / 10 / 2019
at the

7. Cơ quan cấp Đại sứ quán Việt Nam tại Hoa Kỳ
by

8. Số 3985 / HPH/2019
Nº

Ký tên và đóng dấu
Signature and seal/stamp

Tham tán

Quản Thị Kiều Anh



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 ký và đóng con dấu của Bộ Y tế và Dịch vụ Nhân sinh Hoa Kỳ, và rằng con Dấu này được tin tưởng hoàn toàn.*

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

Để chứng thực, tôi, Michael R. Pompeo, Bộ trưởng Ngoại giao, đã cho phép đóng dấu của Bộ Ngoại giao và tên của mình được ký bởi Quan chức Hợp pháp hoá của Bộ trên, tại Thành phố Washington, District of Columbia ngày 17/10/2019.

(đã ký và đóng dấu)

Michael R. Pompeo
Bộ trưởng Bộ Ngoại giao
Cán bộ Lãnh sự,
Bộ Ngoại giao

Chứng thực ông Hồ Anh Vũ, Bí thư thứ hai, Đại sứ quán CHXHCN Việt Nam tại Hợp chúng quốc Hoa Kỳ, đã ký trước mặt tôi.

Ngày 22 tháng 10 năm 2019

TL. Đại sứ
Tham tán



Quản Thị Kiều Anh

Tôi, Hồ Anh Vũ, Bí thư thứ hai, Đại sứ quán 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 22 tháng 10 năm 2019

Người dịch

Hồ Anh Vũ



VNM 19436

U.S. Food & Drug Administration
10881 New Hampshire Avenue
Silver Spring, MD 20910
www.fda.gov

Certificate No. 14567-9-2019

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

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

SAM MEDICAL PRODUCTS
12200 SW Tualatin Road Suite 200
Tualatin, OR USA 97062

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 September 17, 2019 to September 16, 2021.



Application No. 14567-9-2019

Application to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

SAM MEDICAL PRODUCTS
12200 SW Tualatin Road
Suite 200
Tualatin, OR USA 97062

Name of Product(s)

SAM® SPLINT

SP500-CH-EN, SAM® Splint – 9in (22.9cm) Charcoal
SP500-OB-EN, SAM® Splint – 9in (22.9cm) Orange/Blue
SP500-OB-EF, SAM® Splint – 9in (22.9cm) Orange/Blue
SP502-CH-EN, SAM® Splint – 18in (45.7cm) Charcoal
SP502-OB-EN, SAM® Splint – 18in (45.7cm) Orange/Blue
SP502-OB-EF, SAM® Splint – 18in (45.7cm) Orange/Blue
SP502-OB-DE, SAM® Splint – 18in (45.7cm) Orange/Blue
SP504-OB-EN, SAM® Splint – 24in (61.0cm) Orange/Blue
SP504-OB-EF, SAM® Splint – 24in (61.0cm) Orange/Blue
SP506-CH-EN, SAM® Splint – 36in (91.4cm) Rolled, Charcoal
SP506-CH-EF, SAM® Splint – 36in (91.4cm) Rolled, Charcoal
SP506-CH-DE, SAM® Splint – 36in (91.4cm) Rolled, Charcoal
SP506-OB-EN, SAM® Splint – 36in (91.4cm) Rolled, Orange/Blue
SP506-OB-EF, SAM® Splint – 36in (91.4cm) Rolled, Orange/Blue
SP506-OB-DE, SAM® Splint – 36in (91.4cm) Rolled, Orange/Blue
SP507-CH-EN, SAM® Splint – 36in (91.4cm) Flatfold, Charcoal
SP507-CH-EF, SAM® Splint – 36in (91.4cm) Flatfold, Charcoal
SP507-CH-DE, SAM® Splint – 36in (91.4cm) Flatfold, Charcoal
SP507-OD-EN, SAM® Splint – 36in (91.4cm) Flatfold, Olive Drab
SP507-OB-EN, SAM® Splint – 36in (91.4cm) Flatfold, Orange/Blue
SP507-OB-EF, SAM® Splint – 36in (91.4cm) Flatfold, Orange/Blue
SP507-OB-DE, SAM® Splint – 36in (91.4cm) Flatfold, Orange/Blue
SP508-CH-EN, SAM® Splint – 36in (91.4cm) Extra Large, Flatfold, Charcoal
SP508-OB-EN, SAM® Splint – 36in (91.4cm) Extra Large, Orange/Blue
SP508-OB-EF, SAM® Splint – 36in (91.4cm) Extra Large, Orange/Blue
SP508-OB-DE, SAM® Splint – 36in (91.4cm) Extra Large, Orange/Blue
SP526-OB-EN-543, SAM® Vet Splint – 36in (91.4cm) Rolled, Orange/Blue
SP510-OB-EN, SAM® Finger Splint, Orange/Blue with logo
SP512-OB-DE, SAM® Splint – 1ea 36in (91.4cm), 1ea 18in (45.7cm), 2ea Finger Splints
SS540-EN, SAM® Soft Shell Splint – 9in (22.9cm)
SS541-EN, SAM® Soft Shell Splint – 9in (22.9cm) Extra Large
SS542-EN, SAM® Soft Shell Splint – 12in (30.5cm)
SS543-EN, SAM® Soft Shell Splint – 12in (30.5cm) Extra Large
SS544-EN, SAM® Soft Shell Splint – 15in (38.1cm)
SS545-EN, SAM® Soft Shell Splint – 15in (38.1cm) Extra Large
SS546-EN, SAM® Soft Shell 6 pk: 2ea 9in (22.9cm), 12in (30.5cm), 15in (38.1cm)
SS547-EN, SAM® Soft Shell 6 pk: 2ea 9in (22.9cm) XL, 12in (30.5cm) XL, 15in (38.1cm) XL
ST560-EN, SAM® Sugar Tong Splint, Adult – 37in (94.0cm)
ST561-EN, SAM® Sugar Tong Splint, Pediatric – 23in (58.4cm)
ST562-EN, SAM® Sugar Tong Splint, Adult Extra Large – 37in (94.0cm)

Chito-SAM® HEMOSTATIC DRESSING

CT100-A-EN, Chito-SAM100, 4in (10.2cm) x 4in (10.2cm) Single Ply
CT100-B-EN, Chito-SAM100, 3in (7.6cm) x 4ft (122cm) Z-fold
CT100-C-EN, Chito-SAM100, 3in (7.6cm) x 6ft (183cm) Z-fold

SAM® CHEST SEAL PNEUMOTHORAX DRESSING

CS200-EN, SAM® Chest Seal with Valve, 1ea
CS201-EN, SAM® Chest Seal without Valve, 2ea
CS202-EN, SAM® Chest Seal Valved 2.0, 1ea



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03-EN, SAM® Chest Seal Combo, 1ea Chest Seal Valved 2.0 & 1ea Chest Seal without Valve

SAM® PELVIC SLING II

PS300-OB-EN, SAM® Pelvic Sling Small, 27in-45in (69cm-114cm) Hip Circumference
PS301-OB-EN, SAM® Pelvic Sling Standard, 32in-50in (81cm-137cm) Hip Circumference
PS302-OB-EN, SAM® Pelvic Sling Large, 36in-54in (91cm-137cm) Hip Circumference
PS301-OD-EN, SAM® Pelvic Sling Military, 32in-50in (81cm-137cm) Hip Circumference

SAM® JUNCTIONAL TOURNIQUET (SJT)

JT400-EN, SJT Belt with 2ea TCD, 1ea Auxiliary Strap, Extender & Hand Pump
JT401-EN, SJT Belt with 1ea TCD & Hand Pump
JT402-EN, SJT Trainer

SAM® XT EXTREMITY TOURNIQUET (SAM XT)

XT600-BK-EN, SAM® XT Tactical Black
XT600-BL-EN, SAM® XT Hi-Viz Blue
XT600-OR-EN, SAM® XT Hi-Viz Orange

SAM® Bleeding Control Kit

KT901-V-EN, Bleeding Control Kit - Vacuum Sealed
KT901-NV-EN, Bleeding Control Kit - Not Vacuum Sealed

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



