



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 12485-6-2018

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
27350 SW 95th Ave Ste 3038 Bldg 30
Wilsonville, OR USA 97070

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from July 02, 2018 to July 01, 2020.





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

Name of Manufacturer

SAM MEDICAL PRODUCTS
27350 SW 95th Ave Ste 3038 Bldg 30
Wilsonville, OR USA 97070

Name of Product(s)

SAM® EXTREMITY SPLINT

SC042668, SAM® Soft Shell Splint – 9in (22.9cm)
SC042668XL, SAM® Soft Shell Splint – 9in (22.9cm) Extra Large
SC062470, SAM® Soft Shell 6 pk. 2ea 9in (22.9cm), 12in (30.5cm), 15in (38.1cm)
SC062470XL, SAM® Soft Shell 6 pk: 2ea 9in (22.9cm) XL, 12in (30.5cm) XL, 15in (38.1cm) XL
SC121802, SAM® Soft Shell Splint – 15in (38.1cm)
SC121802XL, SAM® Soft Shell Splint – 15in (38.1cm) Extra Large
SC122069, SAM® Soft Shell Splint – 12in (30.5cm)
SC122069XL, SAM® Soft Shell Splint – 12in (30.5cm) Extra Large
SP1005F, SAM® Splint – 9in (22.9cm) Orange/Blue
SP1007F, SAM® Splint – 9in (22.9cm) Charcoal
SP1109F, SAM® Splint – 36in (91.4cm) Flatfold, Charcoal
SP1109R, SAM® Splint – 36in (91.4cm) Rolled, Charcoal
SP1109XL, SAM® Splint – 36in (91.4cm) Extra Large, Flatfold, Charcoal
SP1110F, SAM® Splint – 36in (91.4cm) Flatfold, Olive Drab
SP1115R, SAM® Splint – 36in (91.4cm) Rolled, Charcoal/Blue
SP1121F, SAM® Splint – 36in (91.4cm) Flatfold, Orange/Blue
SP1121FXL, SAM® Splint – 36in (91.4cm) Extra Large, Orange/Blue
SP1121R, SAM® Splint – 36in (91.4cm) Rolled, Orange/Blue
SP1213L, SAM® Finger Splint, Orange/Blue with logo
SP1410F, SAM® Splint – 18in (45.7cm) Orange/Blue
SP1412F, SAM® Splint – 18in (45.7cm) Charcoal
SP3003R, SAM® Vet Splint – 36in (91.4cm) Rolled, Orange/Blue
SPSPLINTKIT02, SAM® Splint – 1ea 36in (91.4cm), 1ea 18in (45.7cm), 2ea Finger Splints
ST052106, SAM® Sugar Tong Splint, Adult – 37in (94.0cm)
ST052106XL, SAM® Sugar Tong Splint, Extra Large – 37in (94.0cm)
ST052106P, SAM® Sugar Tong Splint, Pediatric – 23in (58.4cm)

SAM® PELVIC SLING II

SL556652-SM, Small Hip Circumference
SL556652, Standard Hip Circumference
SL556652-OD, Standard Hip Circumference, Olive Drab
SL556652-LG, Large Hip Circumference

SAM® CHEST SEAL PNEUMOTHORAX DRESSING

CS062010, SAM® Chest Seal with Valve, 1 ea
CS062011, SAM® Chest Seal without Valve, 2ea
CS062013, SAM® Chest Seal Valved 2.0, 1 ea
CS062014, SAM® Chest Seal Combo, 1ea Chest Seal with Valve, 1ea Chest Seal without Valve

Chito-SAM® HEMOSTATIC DRESSING

CTS100-04, Chito-SAM100, 4in (10.2cm) x 4in (10.2cm) Single Ply
CTS100-44, Chito-SAM100, 3in (7.6cm) x 4ft (122cm) Z-fold
CTS100-06, Chito-SAM100, 3in (7.6cm) x 6ft (183cm) Z-fold
CTS100-10, Chito-SAM100, 3in (7.6cm) x 10ft (305cm) Z-fold

SAM® JUNCTIONAL TOURNIQUET (SJT)

SJT101, SJT Belt with 1ea TCD & Hand Pump
SJT102, SJT Belt with 2ea TCDs, 1ea Auxiliary Strap, Extender & Hand Pump
SJT111, 1ea TCD & Hand Pump

SAM® XT EXTREMITY TOURNIQUET (SAM XT)





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SAM XT-B, Hi-Viz Blue

SAM XT-C, High-Viz Orange

SAM XT-M, Tactical Black

SAM® Bleeding Control Kit

KT900-BV, Bleeding Control Kit Basic

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

