

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

CE

Product Family: SAM® Splint

Trade Names: SAM® Splint, SAM® Finger Splint, SAM® Soft Shell™, SAM® Sugar Tong™ Splint,

SAM® Vet Splint

Catalog Numbers:

SC042668: Soft Shell® Splint 9in (22.9cm)

SC042668XL: Soft Shell® Splint 9in (22.9cm) Extra

Large

SC062470: Soft Shell® 6 pack: 2 ea 9in (22.9cm),

12in (30.5cm), 15in (38.1cm)

SC062470XL: Soft Shell® 6 pack: 2 ea 9in (22.9cm)

XL, 12in (30.5cm) XL, 15in (38.1cm)

XL

SC121802: Soft Shell® Splint 15in (38.1cm)

SC121802XL: Soft Shell® Splint 15in (38.1cm)

Extra Large

SC122069: Soft Shell® Splint 12in (30.5cm)

SC122069XL: Soft Shell® Splint 12 in (30.5cm)

Extra Large

SP1005F: SAM® Splint 9in (22.9cm)

SP1007F: SAM® Splint 9in (22.9cm) Charcoal

SP1109F: SAM® Splint 36in (91.4cm) Flatfold,

Charcoal

SP1109R: SAM® Wrist Splint 36in (91.4cm) Rolled,

Charcoal

SP1109XL: SAM® Wrist 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

SP1410F: SAM® Junior Splint 18in (45.7cm)

Orange/Blue

SP1412F: SAM® Junior Splint 18in (45.7cm) Charcoal

SP3003R: SAM® Vet Splint 36in (91.4cm)

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)

ST052106P, SAM® Sugar Tong™ Splint, Pediatric

23in (58.4cm)

Description: The SAM® Splint products are malleable splints built from a thin core of aluminum alloy

adhered between two layers of foam. The SAM® Splint is extremely pliable and when bent into any of three simple curves, becomes rigid to provide support for injured limbs.

Classification/Rule:

Class I, by Annex IX, Rule 1

Generic Name:

Splint, mouldable

Annex VII

Conformity Assessment Route: Notified Body:

NSAI (NB # 0050)

SAM Medical Products declares under its sole responsibility that the above products to which this declaration relates, and which bear the CE Marking, are in conformity with the applicable requirements of EC Directive 93/42/EEC of 14 June 1993.

Manufacturer:

SAM Medical Products 27350 SW 95th Ave. Suite 3038 Wilsonville, OR 97070, U.S.A.

TEL: +1 503-639-5474 FAX: +1 503-639-5425

Signature:

Jeff Lipps, Director QA/RA

EU Authorized Representative:

Emergo Europe Molenstraat 15

2513 BH, The Hague, The Netherlands

TEL: +31 (0)70 345-8570 FAX: +31 (0)70 346-7299

Date: 2016-07-09