

SAM® Splint Declaration of Conformity

EUDOC-0001 Valid through: 2024-06-23

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EU DECLARATION OF CONFORMITY AS PER ANNEX IV OF THE REGULATION (EU) MDR 2017/745

Manufacturer:



SAM® Medical Products

12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

Tel: + 1 (503) 639-5474 | Fax: +1 (503) 639-5425

quality@sammedical.com

Single Registration Number (SRN): US-MF-000002589

EU Authorized Representative:



Emergo Europe

Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Tel: +31 (0)70 345 8570 emergoeurope@ul.com

Single Registration Number (SRN): NL-AR-000000116

Product Family Name

SAM® Splint

Basic UDI-DI:

0822045SP01US (see details in Table 1 attached)

Device(s) concerned:

This Declaration applies to all devices and variants included within the *SAM*[®] *Splint Product Family* (see details in Table 1 attached).

Intended Purpose:

The SAM Splint is intended to temporarily immobilize extremities following traumatic injury.

Risk Class per Annex VIII:

Class I (non-sterile) as per Rule 1

GMDN Code

63273 (First aid limb splint, mouldable)

EMDN Code

M03050202 (Synthetic Cast Bandages and Splints)

Notified Body:

Not applicable.

Class I (non-sterile, non-measuring) devices are not reviewed by a Notified body.

Conformity Assessment Route:

SAM Medical® Products utilizes Annex II and Annex III Technical Documentation (including PMS) for Class I EU medical devices and issues a Declaration of Conformity (self-certification).

Applicable CE Certificate(s):

Not applicable - Class I (non-sterile) devices are self-certified.

Standards and Common Specifications (CS):

This certificate further declares that the products covered herein also comply with the applicable requirements of relevant standards and Common Specifications specified in Table 2.

This declaration of conformity is issued under the sole responsibility of SAM $^{\odot}$ Medical Products. We hereby declare that the medical devices specified above meet the applicable provisions of the Medical Devices Regulation (EU) MDR 2017/745.

All supporting documentation is retained at the premises of the manufacturer.

Person authorized to sign on behalf of SAM® Medical Signature & date:

Name: Jeff Lipps

Position: Director RA/QA, SAM® Medical Products

Products: Place of Issue: 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

2021-06-23



SAM® Splint Declaration of Conformity

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Table 1: Medical devices and variants included in the SAM® Splint Product Family

00822045428737 AM WRIST SPLINT 9IN FLAT CHARCOAL Case SP500-CH-EN	Basic UDI-DI	GTIN	Product	Packaging Level	SKU
169220454287373		00822045428737			
08922045428727			SAM WRIST SPLINT 9IN FLAT CHARCOAL		SP500-CH-EN
16822045428727 ORANGE/BLUE			SAM WPIST SPLINT OIN FLAT		
0892204548925 SAM JUNIOR SPLINT 18IN FLAT CHARCOAL Case C					SP500-OB-EN
108220454289025 SAM JUNIOR SPLINT 18IN FLAT CHARCOAL Case SP502-CB-DE			ONANGE/BLUE		
			SAM JUNIOR SPLINT 18IN FLAT CHARCOAL		SP502-CH-EN
10822045000985 ORANGE/BLUE					
1082/2045/20713 ORANGE/BLUE Case SP502-OB-EN					SP502-OB-DE
10822045428701 ORANGE/BULE					
10822045000995 10822045000995 10822045000992 10822045000922 10822045000022 10822045000022 10822045000022 10822045000022 10822045000022 108220452000022 108220452000022 108220452000022 108220452000022 108220452000022 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528606 1082204528607 10822045286000000000000000000000000000000000000					SP502-OB-FN
10822045000920			ORANGE/BLUE		0, 002 05 211
10822045001022		00822045000995	INDUSTRIAL SPLINT 2/IN FLAT OR	Each	SD504_OR_EN
16822045428681 SAM SPLINT 36IN ROLL CHARCOAL Case SP506-CH-EN		10822045000992	INDOSTRIAL SI LINI 24INI LAT OR	Case	31 304-OD-LIN
10822045428683		00822045001022	CAM COLINT SCIN DOLL CHADCOAL	Each	CDEOG CH DE
16822045428680 SAM SPLINT 36IN ROLL CHARCOAL Case SP506-CH-EN		10822045001029	SAW SPLINT SOIN ROLL CHARCOAL	Case	3P300-CH-DE
16822045428680 SAM SPLINT 36IN ROLL CHARCOAL Case SP506-CH-EN					00-00 011-011
0822045001053			SAM SPLINT 36IN ROLL CHARCOAL		SP506-CH-EN
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10822045000633		10822045000831	TILLDIG OF LINE TORNE LAT ORANGE/DEUE	Case	
10822045000674 RORACO SPLINT 36IN ROLL ORANGE/BLUE		00822045000636	OMS ZOLL SPLINT 26IN DOLL CHARGOAL	Each	
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SP576-DB-DE-801					
10822045000817					SP526-OB-DE-801
10022040000017 OTMINOLIDEOL Case		10822045000817	ORANGE/BLUE	Case	
00822045000766 ALLENSPACH SPLINT 36IN ROLL Each Sp. 790		00822045000766	ALLENSPACH SPLINT 36IN ROLL	Each	CDESC OF THE ZOO
10822045000763 ORANGE/BLUE Case SP526-OB-EN-780		10822045000763		Case	24270-0R-FM-180



SAM® Splint Declaration of Conformity

EUDOC-0001 Valid through: 2024-06-23

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
	00822045000803	SP SERVICES SPLINT 36IN ROLL	Each	SP526-OB-EN-797
	10822045000800	ORANGE/BLUE	Case	
	00822045000445	OMS ZOLL SPLINT 36IN FLAT CHARCOAL	Each	SP527-CH-CZ-802
	10822045000442		Case	
	00822045000469	OMS-ZOLL SPLINT 36IN FLAT	Each	SP527-OB-CZ-721
	10822045000466	ORANGE/BLUE	Case	
	00822045000452	MEDI-KING SPLINT 36IN FLAT	Each	SP527-OB-DE-583
	10822045000459	ORANGE/BLUE	Case	
0822045SP01US	00822045000490	ALLENSPACH SPLINT 36IN FLAT	Each	SP527-OB-DE-781
	10822045000497	ORANGE/BLUE	Case	
	00822045000513	HELBIG SPLINT 36IN FLAT ORANGE/BLUE	Each	SP527-OB-DE-796
	10822045000510		Case	
	00822045000506	SP SERVICES SPLINT 36IN FLAT	Each	SP527-OB-EN-792
	10822045000503	ORANGE/BLUE	Case	
	00822045000568	OMS ZOLL XL 36IN FLAT CHARCOAL	Each	SP528-CH-CZ-789
	10822045000565		Case	
	00822045000582	OMS-ZOLL SPLINT XL 36IN FLAT	Each	SP528-OB-CZ-760
	10822045000589	ORANGE/BLUE	Case	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
	Applied Standards	
EN 1041	Information supplied by the manufacturer of medical devices	2008+A1:2013
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2020
EN ISO 10993-18	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	2020
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016+AC:2018
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	2019
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2016
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015+A1:2020
	Other relevant standards	
EN ISO 17100	Translation services — Requirements for translation services	2015+A1:2017
ASTM F2052	Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment	2015
ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2020
AAMI TIR 12	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	2010
AAMI TIR 30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	2011
	Common Specifications	
-	No common specifications relevant to the device family have been published in OJ at this time.	

EUDOC-0001 SAM Splint DoC (Exp. 2024-06-23)

Final Audit Report 2021-06-23

Created: 2021-06-23

By: Dan Kim (Dan.Kim@sammedical.com)

Status: Signed

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