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® 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 Products:

Signature & date: 2021-06-23

Name: Jeff Lipps
Position: Director RA/QA, SAM® Medical Products
Place of Issue: 12200 SW Tualatin Road, Suite 200, Tualatin, OR 97062, USA

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

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045SP01US	00822045428737	SAM WRIST SPLINT 9IN FLAT CHARCOAL	Each	SP500-CH-EN
	10822045428734		Case	
	00822045428720	SAM WRIST SPLINT 9IN FLAT ORANGE/BLUE	Each	SP500-OB-EN
	10822045428727		Case	
	00822045428928	SAM JUNIOR SPLINT 18IN FLAT CHARCOAL	Each	SP502-CH-EN
	10822045428925		Case	
	00822045000988	SAM JUNIOR SPLINT 18IN FLAT ORANGE/BLUE	Each	SP502-OB-DE
	10822045000985		Case	
	00822045428713	SAM JUNIOR SPLINT 18IN FLAT ORANGE/BLUE	Each	SP502-OB-EN
	10822045428710		Case	
	00822045000995	INDUSTRIAL SPLINT 24IN FLAT OR	Each	SP504-OB-EN
	10822045000992		Case	
	00822045001022	SAM SPLINT 36IN ROLL CHARCOAL	Each	SP506-CH-DE
	10822045001029		Case	
	00822045428683	SAM SPLINT 36IN ROLL CHARCOAL	Each	SP506-CH-EN
	10822045428680		Case	
	00822045001053	SAM SPLINT 36IN ROLL ORANGE/BLUE	Each	SP506-OB-DE
	10822045001050		Case	
	00822045428669	SAM SPLINT 36IN ROLL ORANGE/BLUE	Each	SP506-OB-EN
	10822045428666		Case	
	00822045001077	SAM SPLINT 36IN FLAT CHARCOAL	Each	SP507-CH-DE
	10822045001074		Case	
	00822045428690	SAM SPLINT 36IN FLAT CHARCOAL	Each	SP507-CH-EN
	10822045428697		Case	
	00822045001091	SAM SPLINT 36IN FLAT ORANGE/BLUE	Each	SP507-OB-DE
	10822045001098		Case	
	00822045428676	SAM SPLINT 36IN FLAT ORANGE/BLUE	Each	SP507-OB-EN
	10822045428673		Case	
	00822045428911	SAM SPLINT 36IN FLAT INT'L OD	Each	SP507-OD-EN
	10822045428918		Case	
	00822045428904	SAM SPLINT XL 36IN FLAT CHARCOAL	Each	SP508-CH-EN
	10822045428901		Case	
	00822045001114	SAM SPLINT XL 36IN FLAT ORANGE/BLUE	Each	SP508-OB-DE
	10822045001111		Case	
	00822045428652	SAM SPLINT XL 36IN FLAT ORANGE/BLUE	Each	SP508-OB-EN
	10822045428659		Case	
	00822045428744	SAM FINGER SPLINT ORANGE/BLUE	Each	SP510-OB-EN
	10822045428741		Case	
	00822045428973	ORANGE/BLUE SPLINT KIT 1 36IN, 1 18IN, 2 FINGERS	Each	SP512-OB-DE
	10822045428970		Case	
	00822045000858	OMS-ZOLL SPLINT 18IN FLAT ORANGE/BLUE	Each	SP522-OB-CZ-759
	10822045000855		Case	
	00822045000834	HELBIG SPLINT 18IN FLAT ORANGE/BLUE	Each	SP522-OB-DE-572
	10822045000831		Case	
	00822045000636	OMS-ZOLL SPLINT 36IN ROLL CHARCOAL	Each	SP526-CH-CZ-784
	10822045000633		Case	
	00822045000674	RORACO SPLINT 36IN ROLL ORANGE/BLUE	Each	SP526-OB-DE-512
	10822045000671		Case	
	00822045000704	TINOVAMED SPLINT 36IN ROLL ORANGE/BLUE	Each	SP526-OB-DE-713
	10822045000701		Case	
	00822045000711	SAMARITER SPLINT 36IN ROLL ORANGE/BLUE	Each	SP526-OB-DE-714
	10822045000718		Case	
	00822045000773	HELBIG SPLINT 36IN ROLLED ORANGE/BLUE	Each	SP526-OB-DE-794
	10822045000770		Case	
	00822045000780	ORK SPLINT 36IN ROLLED ORANGE/BLUE	Each	SP526-OB-DE-795
	10822045000787		Case	
	00822045000810	MEDI-KING SPLINT 36IN ROLL ORANGE/BLUE	Each	SP526-OB-DE-801
	10822045000817		Case	
	00822045000766	ALLENSPACH SPLINT 36IN ROLL ORANGE/BLUE	Each	SP526-OB-EN-780
	10822045000763		Case	

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

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Final Audit Report 2021-06-23

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