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® Junctional Tourniquet (SJT)
Basic UDI-DI:	0822045JT01TF (see details in Table 1 attached)
Device(s) concerned:	This Declaration applies to all devices and variants included within the *SAM® Junctional Tourniquet Product Family* (see details in Table 1 attached).
Intended Purpose:	SAM Junctional Tourniquet is intended to control junctional bleeding for up to 4 hours where standard tourniquets cannot be used.
Risk Class per Annex VIII:	Class I (non-sterile) as per Rule 1
GMDN Code	63268 (Emergency junctional haemorrhage compression set)
EMDN Code	V9003 (Tourniquets)
Notified Body:	Not applicable. Class I (non-sterile, non-measuring, non-reusable) 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, non-measuring, non-reusable) 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: Aug 4, 2022

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® Junctional Tourniquet (SJT) Product Family*

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045JT01TF	00822045000353	SJT 2 Target Compression Devices with Hand Pump, Auxiliary Strap, and Extender	Each	JT400- EN
	10822045000350		Case	
	00822045000360	SJT 1 Target Compression Device with Hand Pump	Each	JT401-EN
	10822045000367		Case	
	00822045000346	SJT 402 Trainer	Each	JT402-EN
	10822045000343		Case	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
Applied Standards		
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2020
EN ISO 10993-5	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	2009
EN ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	2013
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+A11:2021
EN ISO 14971	Medical Devices - Application of Risk Management to Medical Devices	2019+A11:2021
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
EN ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements	2021 See Footnote[1]
EN ISO 20417	Medical Devices - Information to be supplied by the manufacturer	2021
EN 62366-1	Medical devices – Part 1: Application of usability engineering to medical devices	2015+A1:2020
Other relevant standards		
ISTA 3A	Packaged Products for Parcel Delivery System Shipment 70 kg (1501b) or Less	2018
MIL-STD-810G	Environmental Engineering Considerations and Laboratory Tests	G
EN ISO 17100	Translation services — Requirements for translation services	2015+A1:2017
Common Specifications		
-	Not available at this time.	

[1]Annex A was utilized for biocompatibility considerations.

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Final Audit Report 2022-08-04

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