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® XT Extremity Tourniquet (SAM® XT)
Basic UDI-DI:	0822045XT01WH (see details in Table 1 attached)
Device(s) concerned:	This Declaration applies to all devices and variants included within the *SAM® XT Extremity Tourniquet Product Family* (see details in Table 1 attached).
Intended Purpose	The SAM® XT Extremity Tourniquet is intended to be applied around a limb to occlude arterial blood flow.
Risk Class per Annex VIII:	Class I (non-sterile) as per Rule 1
GMDN Code	58128 (Arm/leg tourniquet, single use)
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) 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: 2021-06-25

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® XT Extremity Tourniquet Product Family*

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045XT01WH	10822045000206	SAM® XT Extremity Tourniquet – Tactical Black	Case	XT600-BK-EN
	00822045000209		Each	
	10822045000213	SAM® XT Extremity Tourniquet – Hi-Viz Orange	Case	XT600-OR-EN
	00822045000216		Each	
	10822045000220	SAM® XT Extremity Tourniquet – Hi-Viz Blue	Case	XT600-BL-EN
	00822045000223		Each	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
Applied Standards		
EN ISO 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 ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements	2015 See Footnote[1]
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		
-	No common specifications relevant to the device family have been published in OJ at this time.	

[1]Annex A was utilized for biocompatibility considerations.

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Final Audit Report 2021-06-25

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