SAM MEDICAL	SAM® ThoraSite Declaration of Conformity		
	EUDOC-0012-A	Valid through: 2028-12-01	Page 1 of 2

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 regulatory@sammedical.com Single Registration Number (SRN): US-MF-000002589
EU Authorized Representative:	**Emergo Europe** Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands Tel: +31 (0)70 345 8570 emergoeurope@ul.com Single Registration Number (SRN): NL-AR-000000116
Product Family Name	SAM® ThoraSite
Basic UDI-DI:	0822045TS01VG (See details in Table 1 attached)
Device(s) concerned:	This Declaration applies to all devices and variants included within the *SAM® ThoraSite Product Family* (see details in Table 1 attached).
Intended Purpose	An anatomical location aid to identify an appropriate location for lateral thoracostomies in adult and adolescent patients. Not intended for pediatric, or neonatal use.
Risk Class per Annex VIII:	Class I (non-sterile) as per Rule 1
GMDN Code	45018 (Non-implantable needle guide, single-use)
EMDN Code	R9099 (Respiratory and Anesthesia Devices –Other)
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 provision 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: 12-1-2025

Name: Kyle Sims
Position: Director of Research and Product Development, 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 ThoraSite

Basic UDI-DI	GTIN	Product	Packaging Level	SKU
0822045TS01VG	10822045001500	SAM Thorasite Single Selling Unit	Inner Pack	TS200-1P
	00822045001503		Each	

Table 2: Standards and Common Specifications (CS) applied

Standard #	Title	Year / Version
Applied Standards		
EN ISO 20417	Medical Devices - Information supplied by the manufacturer	2021
EN ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing 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
Other relevant standards		
EN ISO 17100	Translation services — Requirements for translation services	2015+A1:2017
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2021 See Footnote[1]
Common Specifications		
-	No common specifications relevant to the device family have been published in OJ at this time.	

[1]Test methods utilized for accelerated aging test