Manufacturer's EU Declaration of Conformity

Manufacturer:	Safeguard Medical Technologies Ltd.
SRN:	GB-MF-000012038
Address:	The Old Rectory Hope-Under-Dinmore Herefordshire HR6 0PW United Kingdom
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EU Authorised Representative:	Safeguard Technologies Ltd. Wicklow Serviced Offices Eden Gate Centre Delgany, A63 XY89 Co Wicklow, Ireland
SRN:	IE-AR-000008867

declares and guarantees the product

Product Name:	SWAT-T Tourniquet
Intended Use:	The SWAT-T is a non-pneumatic tourniquet designed to stop severe traumatic bleeding before or during transport to a care facility.
Product Code/Number:	PDF165 – SWAT-T Black PDF166 – SWAT-T Orange
Basic UDI-DI	GS1 Code: 5060483571659P

complies with provision of the **MDR 2017/745** which apply to it based on its intended use.

According to the **Annex VIII** of the **MDR 2017/745**, **rule 1**, the product is classified as

Class I, Rule 1 – non-sterile, non-invasive medical device

The appropriate registration has been made to HPRA as the competent authority in Ireland, and the base for the SMT Authorised Representative in the EU.

Safeguard Medical Technologies Ltd. agrees to develop, implement and maintain the post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This declaration is based on the **Annex IV** of **MDR 2017/745**.

The following standards, regulations, guidelines, and state of the art documents have been adhered to by SMT in order to demonstrate compliance of the product with the **Regulation (EU) on Medical Devices 2017/745:**

Regulations and Guidelines	Description
EU MDR 2017/745	EU Regulations for Medical Devices
MDCG 2020-2 rev1	Class I transitional provisions under Article 120 (3 and 4) – (MDR)
MDCG 2019-15	Guidance notes for manufacturers of class I medical devices
MDCG 2019-9	Summary of safety and clinical performance A guide for manufacturers and notified bodies

State of the Art	Description
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
EN ISO 10993-1:2018	Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological Evaluation of Medical Devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-4:2017	Biological Evaluation of Medical Devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018	Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity
EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 62366-1:2015	Medical Devices - Part 1: Application of usability engineering to medical devices
EN ISO 31000:2018	Risk Management Principles and Guidelines
EN ISO 31010:2019	Risk Management: Risk Assessment Techniques

Harmonised Standards with Regulation (EU) 2017/745 on Medical Devices	Description
EN ISO 10993-23:2021	Biological Evaluation of Medical Devices - Part 23: Tests for irritation
EN ISO 13485:2016, A11:2021	Medical Devices - Quality System Requirements - for regulatory purposes
ISO 15223-1:2021	Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements

This declaration of conformity is issued under the sole responsibility of Safeguard Medical Technologies Ltd as the Legal Manufacturer of the Product.

Signed Eva Havelkova

Date: Jul 13, 2022

Place: Herefordshire

Eva Havelková - QA/RA Director, Safeguard Medical Technologies Ltd

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479_22	0	13/07/2022	First issue of document

Registered Office Address: Safeguard Medical Technologies Limited
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Company Number 8623209

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