H&H MEDICAL CORPORATION
328 McLaws Circle
Williamsburg, VA
23185
804-642-3663
hhmedcorp.com

Manufacturer's EU Declaration of Conformity

Manufacturer:	H&H Medical Corporation
SRN:	TBD
Address:	328 McLaws Circle Williamsburg, Virginia 23185 United States
Email:	Michellej@safeguardmedical.com
Telephone:	1-804-642-6336
EU Authorised Representative:	Safeguard Technologies Ltd. Willow Grove Delgany, Co Wicklow, A63 XY89, Ireland

declares and guarantees the product

Product Name:	SWAT-T Tourniquet
Intended Use:	A non-pneumatic tourniquet designed to stop severe traumatic bleeding before or during transport to a care facility
Product Code/Number:	SWAT-T-ORG SWAT-T-BLK
Basic UDI-DI:	00857048006224

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 H&H Medical Authorised Representative in the EU.

H&H Medical Corporation 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**.

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The following standards, regulations, guidelines, and state of the art documents have been adhered to by H&H Medical 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 13485:2016	Medical Devices - Quality System Requirements - for regulatory purposes
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied
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**
N/A	N/A

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This declaration of conformity is issued under the sole responsibility of H&H Medical Corporations the Legal Manufacturer of the Product.

Signed Michelle Jones-Black Date, Place: 05/25/2021, Williamsburg, VA.

Quality Assurance Analyst

Version History

DC Number	Revision	Date	Description of Change
NEW	0	05/25/2021	First issue of document