Manufacturer's EU Declaration of Conformity

Manufacturer:	**6:8 Medical Solutions LLC**
SRN:	N/A
Address:	1605 American Way Myrtle Beach SC 29577
Email:	info@68medicalsolutions.com
Telephone:	(843) 999-0228
EU Authorised Representative:	Real8 Medtech Limited
SRN:	**IE-AR-000042902**
Address:	5 Wendon Drive Delgany Wood, Delgany, Wicklow, Ireland A63 CD42
Email:	info@real8medtech.com
Telephone:	IE-AR-000042902

declares and guarantees the product

Product Name:	THE ADVANTAGE
Intended Purpose:	The ADVANTAGE is intended to be used to control minor to life threatening bleeding.
Product Code/Number:	• TADV-01 • TADV-02
Basic UDI-DI	0081018834TADVRC

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 4**, the product is classified as

Class I, Rule 4 – 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 6:8´s Authorised Representative in the EU.

6:8 Medical Solutions 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 6:8 Medical Solutions 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

State of the Art	Description
EN ISO 31000:2018	Risk Management Principles and Guidelines
EN ISO 31010:2019	Risk Management: Risk Assessment Techniques
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Harmonised Standards with Regulation (EU) 2017/745 on Medical Devices	Description
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

This declaration of conformity is issued under the sole responsibility of 6:8 Medical Solutions as the Legal Manufacturer of the Product.

Signed Uriah Popp Uriah Popp (May 20, 2025 11:47 EDT) Date: 20-May-2025 Place: Myrtle Beach SC

Version History

DC Number	Revision	Date	Description of Change
34/2025	0	30-Apr-2025	First Issue of Document

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