Manufacturer's UK Declaration of Conformity

Manufacturer:	**6:8 Medical Solutions LLC**
Address:	1605 American Way Myrtle Beach SC 29577
Email:	info@68medicalsolutions.com
Telephone:	(843) 999-0228

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

complies with provision of the requirements of the relevant annexes to **EC Directive 93/42/EEC**, which have been modified by Schedule 2A to the **UK MDR 2002**.

According to the **Annex IX** of the **Council Directive 93/42/EEC, rule 4**, the product is classified as

Class I, Rule 4 – non-sterile, non-invasive medical device

The appropriate registration has been made to MHRA as the competent authority in the UK.

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 VII** of **EC Directive 93/42/EEC.**

The listed medical device, its design, manufacturing, distribution complies with the following designated standards:

Regulations, Guidelines, State of the Art	**Description**
UK MDR 2002	The Medical Devices Regulations 2002
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

Regulations, Guidelines, State of the Art	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.

Signed Uriah Popp Uriah Popp (May 21, 2025 12:45 EDT) Date: 21-May-2025

Version History

DC Number	Revision	Date	Description of Change
50/2025	0	21-May-2025	First Issue of Document

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