DECLARATION OF CONFORMITY

1 Manufacturer

Compression Works, LLC
1634-A Montgomery Hwy, #115
Birmingham, AL 35216-4902
United States
(800) 988-4052
SRN US-MF-000021119
www.compressionworks.com

2 European authorized representative:

Elara Pharmaservices Europe Ltd
Office 107, Regus Block 1,
Blanchardstown, Dublin, D15 AKK1,
Ireland
SRN IE-AR-000011852

3 Product(s) (name, type or model/batch number, etc.):

Name: Abdominal Aortic & Junctional Tourniquet (Stabilized) - AAJT-S

Model Number: AAJT-S001

4 The product(s) described above is in conformity with:

Title	Document No.
Medical Device Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

5 Additional information

Conformity Assessment Procedure: According to Annex IX of th EU MDR. Based on the requirements for a Class I (non-sterile) medical device as per MDR article 52.

Classification: According to Annex VIII of the EU MDR, Class I (non-sterile), Rule 5.
This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

2024-07-08

(Place & date of issue (yyyy-mm-dd))

Scott Dodson, Chief Executive Officer

(name; function and signature of manufacturer)

Appendix

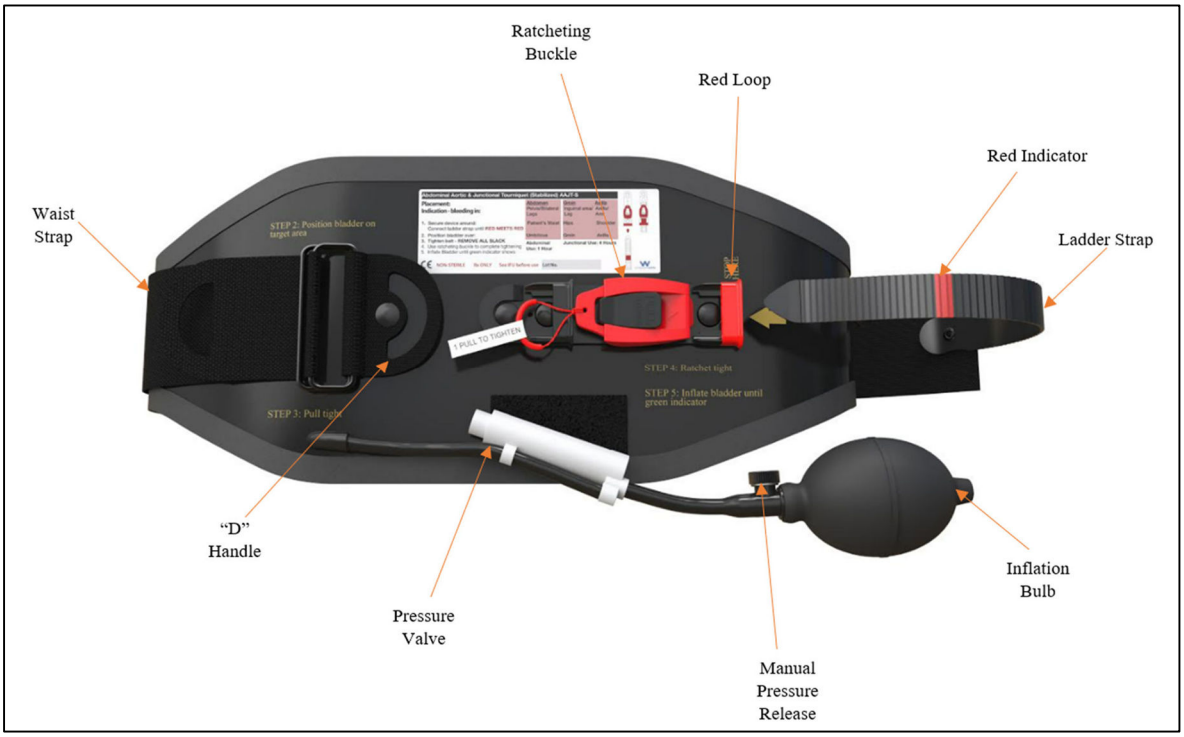
List of devices.

Product name	Trade name	Product code/ catalogue number	Intended purpose	Risk class/ rule[1]	Basic UDI-DI[2] / UDI-DI
Abdominal Aortic & Junctional Tourniquet (Stabilized) - AAJT-S.	Abdominal Aortic & Junctional Tourniquet (Stabilized) - AAJT-S	AAJT-S001	Control of difficult bleeding in the pelvis, inguinal area and axilla.	According to Annex VIII of the EU MDR, Class I (non-sterile), Rule 5	Basic UDI-DI – 08600022275AAJTS0014G UDI-DI – 00860002227504

[1] See risk classification in Medical Device Regulation, annex VIII

[2] Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI

Abdominal Aortic Junctional Tourniquet (Stabilized) – AAJT-S



List of Standards:

- EN ISO 14971:2019; RISK ASSESSMENT
- EN 62366:2015 USABILITY
- EN ISO 10993 SERIES: BIOLOGICAL EVALUATION