

#### **DECLARATION OF CONFORMITY**

### 1 Manufacturer

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

### 2 European authorized representative:

Elara Pharmaservices Europe Ltd 239 Blanchardstown, Corporate Park, Ballycoolin, Dublin D15KV21

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

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

Model Number: AAJT-S001

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

<u>Title</u>	Document No.
Medical Device Regulation	(EU) 2017/745

# 5 Additional information

Conformity assessment procedure: Medical Device Regulation, Annex II and III

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

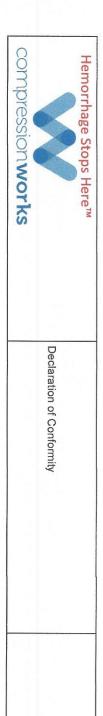
Dalles, Texas USA

2022-03-07

Scott Dodson, Chief Executive Officer

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

(name; function and signature of manufacturer)



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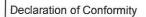
# **Appendix**

# List of devices.

Product name	Trade name	Product code/ catalogue number	Intended purpose	Risk class/ rule <sup>1</sup>	class/ Basic UDI-DI <sup>2</sup>	First date of CE- compliance
Abdominal Aortic	Abdominal Aortic   Abdominal Aortic   AAJT-S001	AAJT-S001	Control of difficult	Class I, per	Basic UDI-DI -	
& Junctional	& Junctional		bleeding in the pelvis,	MDR	008600002227504VY	
Tourniquet	Tourniquet		inguinal area and axilla.	Annex VIII,		
(Stabilized) -	(Stabilized) -			Rule 1	UDI-DI -	
AAJT-S.	AAJT-S				00860002227504	

<sup>&</sup>lt;sup>1</sup> See risk classification in Medical Device Regulation, annex VIII

<sup>2</sup> 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

