

Declaration of Conformity

DoC Ver 1

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DECLARATION OF CONFORMITY

1 Manufacturer

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

Actor ID/SRN: US-MF-000021119

2 <u>UK Representative:</u>

Callisto Consulting Ltd

Iron Farm, 7 Grimesgate

Diseworth Derby DE74 2QD United Kingdom

EU Representative

Elara Pharmaservices Europe, Ltd 239 Blanchardstown, Corporate Park,

Ballycoolin, Dublin

D15KV21 Ireland

Actor ID/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-\$001

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

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

5 Additional information

Conformity assessment procedure: According to Annex II & III of the mentioned Regulation.

Classification: Classified as class I according to rule 1 of Annex VIII.

We, **COMPRESSION WORKS**, **INC**, hereby declare under our sole responsibility that the medical device specified above and in the attachment is in compliance with the above Directive.

05 APRIL ZOZZ

Scott Dodson, Chief Executive Officer

vs 2021-XV

Declaration form: Standard ISO/IEC 17050-1:2010

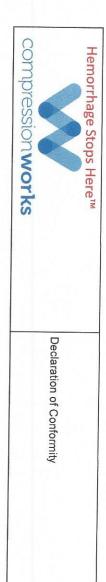


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(Place & date of issue (yyyy-mm-dd))

(name; function and signature of manufacturer)



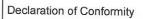
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Appendix

List of devices.

Product name	Trade name	Product code/	Intended purpose	Risk class/ rule ¹	Basic UDI-DI ² / UDI-DI
		catalogue			
		number			
Abdominal	Abdominal Aortic &	AAJT-S001	AAJT-S001 Control of difficult bleeding in	Classified as class I	Basic UDI-DI -
AOITIC &	Junctional Lourniquet		the pelvis, inguinal area and	according to rule 1;	08600022275AAJTS0014G
Junctional	(Stabilized) -AAJT-S		axilla.	Annex VIII of the	200
(Stabilized)				Medical Device	UDI-DI - 00860002227504
(Stabilized) -				Regulation	
AAJT-S.				(

¹ See risk classification in Medical Devices Directive, as amended.
² Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the suppliers 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

