

DECLARATION OF CONFORMITY

1 Manufacturer

Compression Works, Inc
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 United States
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Actor ID/SRN: US-MF-000021119

2 UK Representative:

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 Iron Farm, 7 Grimesgate
 Diseworth
 Derby
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 United Kingdom

EU Representative

Elara Pharmservices 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-S001

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

Title	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 2022


 Scott Dodson, Chief Executive Officer

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

(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.	Classified as class I according to rule 1 ; Annex VIII of the Medical Device Regulation	Basic UDI-DI – 08600022275AAJTS0014G UDI-DI – 00860002227504

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

