EU DECLARATION OF CONFORMITY

Legal Manufacturer	Name: Teleflex Medical Address: IDA Business & Technology Park Dublin Road, Athlone Co. Westmeath Ireland Single Registration Number (SRN): N/A
Authorized Representative	Name: N/A Address: N/A Single Registration Number (SRN): N/A
Notified Body	Name: N/A Class I self-certified Identification Number: N/A Class I self-certified

Product Name	Product Classification	Classification Rule	Conformity Assessment Route (s)	EC Certificate(s) No
T-POD Pelvic Stabilization Devices	I	Annex VIII Rule 4	Annex IV	N/A

Teleflex Medical declares that the above documented product(s) meets the provisions of Regulation (EU) 2017/745. This declaration is issued under the sole responsibility of Teleflex Medical and authorizes Teleflex Medical to affix the CE-marking to the products listed herein.

Intended Purpose: The T-POD Device provide circumferential compression to the pelvis in patients with suspected pelvic fracture for pelvic stabilization which may reduce blood loss and pain.

Basic UDI-DI	Product Name	Product Code	EMDN /CND Code	Manufacturing Site & Address (If not required, mark N/A)	Date CE Mark Affixed by Teleflex Medical
08019020000000000000021JY	T-POD Responder	T-PODR	M030599	AccuMED Corp. Building 3, 4, 6, 8 and 9 Zona Franca de Nigua, Nigua, 11117 San Cristobal,	03 July 2018

				Dominican Republic	
08019020000 00000000002 1JY	T-POD Combat	T-PODC	M030599	AccuMED Corp. Building 3, 4, 6, 8 and 9 Zona Franca de Nigua, Nigua, 11117 San Cristobal, Dominican Republic	03 July 2018

** Indicates the item is within the scope of and in compliance with European Directive 2011/65/EU, the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment.*

Approvals

Name and Title of Approver:	Ida Foley Senior Manager Quality Systems
Signature of Approver:	Ida Foley
Date Approved:	16-Dec-2020
Place of Issue:	Tullamore, County Offaly, Ireland

Change History for Declaration of Conformity:

Revision	Date	Reason for Revision
AA	See COF2783	Initial release of EU-DOC for MDR Compliance