

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 735219 R000

Manufacturer: Bolton Medical, Inc.

Address:

799 International Parkway
Sunrise
Florida
33325
USA

Single Registration Number: US-MF-000002287

EU Authorised Representative: Terumo Europe N.V.

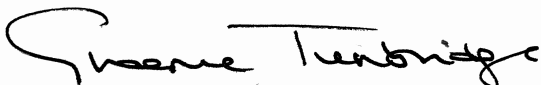
Address:

Interleuvenlaan 40
3001 Leuven
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-10-12**

Current Issue Date: **2022-10-12**

Starting Validity Date: **2022-10-12**

Expiry Date: **2027-10-11**

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Device Name: TREO Abdominal Stent-Graft System

Intended Purpose as per the Instructions for Use:

The TREO Abdominal Stent-Graft System is intended for the endovascular treatment of infrarenal abdominal aortic and aorto-iliac aneurysms.

Risk Classification: Class III Implantable

Basic UDI-DI: 0843604539AAA3E

Type: MDN 1101

Catalogue Number	Device Name	Model
28-B2-20-080S	TREO	Bifurcate
28-B2-20-100S	TREO	Bifurcate
28-B2-20-120S	TREO	Bifurcate
28-B2-22-080S	TREO	Bifurcate
28-B2-22-100S	TREO	Bifurcate
28-B2-22-120S	TREO	Bifurcate
28-B2-24-080S	TREO	Bifurcate
28-B2-24-100S	TREO	Bifurcate
28-B2-24-120S	TREO	Bifurcate
28-B2-26-080S	TREO	Bifurcate
28-B2-26-100S	TREO	Bifurcate
28-B2-26-120S	TREO	Bifurcate
28-B2-28-080S	TREO	Bifurcate

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28-B2-28-100S	TREO	Bifurcate
28-B2-28-120S	TREO	Bifurcate
28-B2-30-080S	TREO	Bifurcate
28-B2-30-100S	TREO	Bifurcate
28-B2-30-120S	TREO	Bifurcate
28-B2-33-080S	TREO	Bifurcate
28-B2-33-100S	TREO	Bifurcate
28-B2-33-120S	TREO	Bifurcate
28-B2-36-080S	TREO	Bifurcate
28-B2-36-100S	TREO	Bifurcate
28-B2-36-120S	TREO	Bifurcate
28-L2-09-080S	TREO	Leg
28-L2-09-100S	TREO	Leg
28-L2-09-120S	TREO	Leg
28-L2-09-140S	TREO	Leg
28-L2-09-160S	TREO	Leg
28-L2-11-080S	TREO	Leg
28-L2-11-100S	TREO	Leg
28-L2-11-120S	TREO	Leg

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Catalogue Number	Device Name	Model
28-L2-11-140S	TREO	Leg
28-L2-11-160S	TREO	Leg
28-L2-13-080S	TREO	Leg
28-L2-13-100S	TREO	Leg
28-L2-13-120S	TREO	Leg
28-L2-13-140S	TREO	Leg
28-L2-13-160S	TREO	Leg
28-L2-15-080S	TREO	Leg
28-L2-15-100S	TREO	Leg
28-L2-15-120S	TREO	Leg
28-L2-15-140S	TREO	Leg
28-L2-15-160S	TREO	Leg
28-L2-17-080S	TREO	Leg
28-L2-17-100S	TREO	Leg
28-L2-17-120S	TREO	Leg
28-L2-17-140S	TREO	Leg
28-L2-17-160S	TREO	Leg
28-L2-20-080S	TREO	Leg
28-L2-20-100S	TREO	Leg

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28-L2-20-120S	TREO	Leg
28-L2-20-140S	TREO	Leg
28-L2-20-160S	TREO	Leg
28-L2-24-080S	TREO	Leg
28-L2-24-100S	TREO	Leg
28-L2-24-120S	TREO	Leg
28-L2-24-140S	TREO	Leg
28-L2-24-160S	TREO	Leg
28-C2-20-040S	TREO	Cuff
28-C2-20-055S	TREO	Cuff
28-C2-20-070S	TREO	Cuff
28-C2-22-040S	TREO	Cuff
28-C2-22-055S	TREO	Cuff
28-C2-22-070S	TREO	Cuff
28-C2-24-040S	TREO	Cuff
28-C2-24-055S	TREO	Cuff
28-C2-24-070S	TREO	Cuff
28-C2-26-040S	TREO	Cuff
28-C2-26-055S	TREO	Cuff

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28-C2-26-070S	TREO	Cuff
28-C2-28-040S	TREO	Cuff
28-C2-28-055S	TREO	Cuff
28-C2-28-070S	TREO	Cuff
28-C2-30-040S	TREO	Cuff
28-C2-30-055S	TREO	Cuff
28-C2-30-070S	TREO	Cuff
28-C2-33-040S	TREO	Cuff
28-C2-33-055S	TREO	Cuff
28-C2-33-070S	TREO	Cuff
28-C2-36-040S	TREO	Cuff
28-C2-36-055S	TREO	Cuff
28-C2-36-070S	TREO	Cuff
28-S2-09-080S	TREO	Straight
28-S2-11-080S	TREO	Straight
28-S2-13-080S	TREO	Straight

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3279415	Issued



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