

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 726874 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.

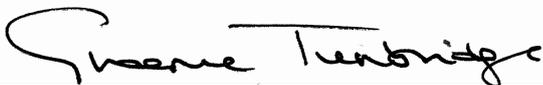
Address:

Interleuvenlaan 40
3001 Leuven
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II 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: **2020-11-23**

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

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

Expiry Date: **2025-11-22**

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
RelayPro Thoracic Stent-Graft System	See MDR 735214
RelayPlus Thoracic Stent-Graft System	See MDR 735216
RelayNBS Plus Thoracic Stent-Graft System	
TREO Abdominal Stent-Graft System	See MDR 735219

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Treo Abdominal Aortic Stent-graft System (Custom Made)	Custom-made Class III implantable
Relay Thoracic Aortic Stent-graft System (Custom Made)	Custom-made Class III implantable

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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
2020-11-23	3167068	First Issue.
2022-02-07	3555977	Supplemented – Addition of RelayPro Thoracic Stent-Graft System to Device Schedule; Addition of Manufacturer SRN
Current	3635806	Supplemented – Addition of RelayPlus and RelayNBS Plus Thoracic Stent-Graft System, and TREO Abdominal Stent-Graft System to Device Schedule. Amended - Addition of Sterigenics Haw River subcontractor; Removal of Vascutek Limited subcontractor. Amended- Change of authorised representative to Terumo Europe N.V.

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 726874 R000

Date: 2022-10-12

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Atex Technologies, Inc. 120 West Monroe Avenue Pinebluff North Carolina 28373-8333 USA	Crucial Supplier
Confluent Medical Technologies, Inc. 47533 Westinghouse Drive Fremont California 94539 USA	Manufacture
Nitinol Devices & Components Costa Rica, S. R. L. Coyol Free Zone, Building B14 El Coyol, Alajuela 20102 Costa Rica	Manufacture
Norman Noble, Inc. 5507 Avion Park Drive Highland Heights Ohio 44143 USA	Manufacture

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Date: 2022-10-12

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics US, LLC 502 Prairie Mine Road Mulberry Florida 33860 USA	Radiation (Gamma Sterilization)
Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	Radiation (Gamma Sterilization)
Terumo Vietnam Co., LTD. Lot 44A-B-C, Quang Minh Industrial Zone Me Linh District Hanoi City Vietnam	Manufacture
Viant Collegeville, LLC a.t.a (formerly) Lake Region Medical 200 West 7th Ave Collegeville Pennsylvania 19426 USA	Manufacture

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