

FORM**CP #: 05365****TITLE: Declaration of Conformity – CE (MDR)****Document #: Form-0418
Rev: E****DECLARATION OF CONFORMITY**

Manufacturer Name:	Bolton Medical, Inc.	
Address:	799 International Parkway Sunrise, Florida 33325 USA	
Single Registration Number (SRN):	US-MF-000002287	
Authorized Representative Name:	Terumo Europe N.V. (EU)	Vascutek Deutschland GmbH (Switzerland)
Address:	Interleuvenlaan 40 3001 Leuven Belgium	Zweigniederlassung Switzerland Bodenackerstrasse 3 8957 Spreitenbach Switzerland
Single Registration Number (SRN):	BE-AR-000001433	CHRN-AR-20001478
Product Name:	TREGO Abdominal Stent-Graft System	
Basic UDI-DI	843604539AAAJN	
UDI-DI Code:	See attached for Complete List	
Product Categories (e.g., coronary stents, stent-grafts):	Abdominal Stent-Graft System	
Indications:	Treatment of infrarenal abdominal aortic aneurysms in adult patients	
Design / Manufacturing Facilities:	Bolton Medical, Inc. 799 International Parkway Sunrise, Florida 33325 USA	
Models / References (Attach list if necessary):	See Attached for Complete List	
Classification (MDR, Annex VIII):	Class III, Rule 8	
Conformity Assessment Route:	Annex IX	
EU Quality Management System Certificate Annex IX Chapter 1 and 3:	MDR 726874	
Issued By (Notified Body Name / Number / Address):	BSI Group The Netherlands B.V. (number 2797) BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands	
EU Technical Documentation Assessment Certificate Annex IX Chapter 2:	MDR 735219	
Issued By (Notified Body Name / Number / Address):	BSI Group The Netherlands B.V. (number 2797)	

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	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Placing Products on the Market as of:	09 October 2015
Other Relevant Codes (e.g., GMDN code)	GMDN: 46777: Abdominal aorta endovascular stent-graft UMDNS 11908: Graft

Declaration:

I, the undersigned, declare that the above mentioned product meets the applicable provisions and conforms to the General Safety and Performance Requirements of Annex I of the following EC Council Regulation:

Medical Device Regulation: COUNCIL REGULATION 2017/745 of 5 April 2017 concerning medical devices

and Article 6 of the Swiss Medical Devices Ordinance.

This Declaration is issued under the sole responsibility of Bolton Medical, Inc.

All supporting documentation is retained under the premises of the manufacturer.

Name:	Title	
	Global VP or Regulatory Affairs:	
Place: Sunrise, Florida, USA	Signature:	Date: 01 Feb 2023

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Complete Listing of Reference Numbers

TREO Abdominal Stent-Graft System

#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN
1	28-B2-20-080S	08436045396709	34	28-C2-26-040S	08436045396976	67	28-L2-15-140S	08436045397423
2	28-B2-20-100S	08436045396785	35	28-C2-26-055S	08436045397058	68	28-L2-15-160S	08436045397492
3	28-B2-20-120S	08436045396860	36	28-C2-26-070S	08436045397133	69	28-L2-17-080S	08436045397225
4	28-B2-22-080S	08436045396716	37	28-C2-28-040S	08436045396983	70	28-L2-17-100S	08436045397294
5	28-B2-22-100S	08436045396792	38	28-C2-28-055S	08436045397065	71	28-L2-17-120S	08436045397362
6	28-B2-22-120S	08436045396877	39	28-C2-28-070S	08436045397140	72	28-L2-17-140S	08436045397430
7	28-B2-24-080S	08436045396723	40	28-C2-30-040S	08436045396990	73	28-L2-17-160S	08436045397508
8	28-B2-24-100S	08436045396808	41	28-C2-30-055S	08436045397072	74	28-L2-20-080S	08436045397232
9	28-B2-24-120S	08436045396884	42	28-C2-30-070S	08436045397157	75	28-L2-20-100S	08436045397300
10	28-B2-26-080S	08436045396730	43	28-C2-33-040S	08436045397003	76	28-L2-20-120S	08436045397379
11	28-B2-26-100S	08436045396815	44	28-C2-33-055S	08436045397089	77	28-L2-20-140S	08436045397447
12	28-B2-26-120S	08436045396891	45	28-C2-33-070S	08436045397164	78	28-L2-20-160S	08436045397515
13	28-B2-28-080S	08436045396747	46	28-C2-36-040S	08436045397010	79	28-L2-24-080S	08436045397249
14	28-B2-28-100S	08436045396822	47	28-C2-36-055S	08436045397096	80	28-L2-24-100S	08436045397317
15	28-B2-28-120S	08436045396907	48	28-C2-36-070S	08436045397171	81	28-L2-24-120S	08436045397386
16	28-B2-30-080S	08436045396754	49	28-L2-09-080S	08436045397188	82	28-L2-24-140S	08436045397454
17	28-B2-30-100S	08436045396839	50	28-L2-09-100S	08436045397256	83	28-L2-24-160S	08436045397522
18	28-B2-30-120S	08436045396914	51	28-L2-09-120S	08436045397324	84	28-S2-09-080S	08436045397539
19	28-B2-33-080S	08436045396761	52	28-L2-09-140S	08436045397393	85	28-S2-11-080S	08436045397546
20	28-B2-33-100S	08436045396846	53	28-L2-09-160S	08436045397461	86	28-S2-13-080S	08436045397553
21	28-B2-33-120S	08436045396921	54	28-L2-11-080S	08436045397195			
22	28-B2-36-080S	08436045396778	55	28-L2-11-100S	08436045397263			
23	28-B2-36-100S	08436045396853	56	28-L2-11-120S	08436045397331			
24	28-B2-36-120S	08436045396938	57	28-L2-11-140S	08436045397409			
25	28-C2-20-040S	08436045396945	58	28-L2-11-160S	08436045397478			
26	28-C2-20-055S	08436045397027	59	28-L2-13-080S	08436045397201			
27	28-C2-20-070S	08436045397102	60	28-L2-13-100S	08436045397270			
28	28-C2-22-040S	08436045396952	61	28-L2-13-120S	08436045397348			
29	28-C2-22-055S	08436045397034	62	28-L2-13-140S	08436045397416			
30	28-C2-22-070S	08436045397119	63	28-L2-13-160S	08436045397485			
31	28-C2-24-040S	08436045396969	64	28-L2-15-080S	08436045397218			
32	28-C2-24-055S	08436045397041	65	28-L2-15-100S	08436045397287			
33	28-C2-24-070S	08436045397126	66	28-L2-15-120S	08436045397355			