

TITLE: Declaration of Conformity – CE (MDD)	Document # Form-0105 Rev G
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DECLARATION OF CONFORMITY	
Manufacturer Name:	Bolton Medical, Inc.
Address:	799 International Parkway Sunrise, Florida 33325 USA
Product Name:	<u>Treovance/TREO Family of Devices:</u> Treovance Abdominal stent-graft with Navitel Delivery System TREO Abdominal Stent-Graft System TREO AUI Stent-Graft System TREO Occluder System
Product Categories (e.g., coronary stents, stent-grafts):	Stent-Graft
Indications:	Treatment of infrarenal abdominal aortic aneurysms in adult patients.
Design / Manufacturing Facilities:	Bolton Medical, Inc. 799 International Parkway Sunrise, Florida 33325 USA European Authorized Representative: Emergo Europe B.V. Prinsessegracht 20 2514 AP The Hague The Netherlands
Models / References (Attach list if necessary):	See Attached for Complete List 28-B1-XX-XXXS, 28-L1-XX-XXXS, 28-C1-XX-XXXS 28-S1-XX-XXXS references for: Treovance Abdominal stent-graft with Navitel Delivery System 28-B2-XX-XXXS, 28-L2-XX-XXXS, 28-C2-XX-XXXS, 28-S2-XX-XXXS references for: TREO Abdominal Stent-Graft System 28-A1-XX-XXXS references for: TREO AUI Stent-Graft System 28-P1-XX-XXXS references for: TREO Occluder System
Classification (MDD, Annex IX):	Class III (as per Rule 8)

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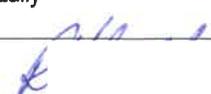
DECLARATION OF CONFORMITY	
Conformity Assessment Route:	Annex II, section 4 is applied for the Design Examination Certificate
Quality System Certificate Number:	CE 716356 (Full Quality Assurance System)
Issued By (Notified Body Name / Number / Address):	BSI Group The Netherlands B.V. (number 2797) BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
EC Design Examination / EC Type Examination Certificate Number:	CE 716636
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
Placing Products on the Market as of:	Treovance Abdominal Stent-Graft with Navitel delivery System (16 April 2013) TREG Abdominal Stent-Graft System (9 Oct 2015) TREG AUI Stent-Graft System (23 Mar 2017) TREG Occluder System (31 Mar 2017)
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 of the following EC Council Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by 2007/47/EC.

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

Name: Robert Lally	Title: Global VP of Regulatory Affairs Sunrise, Florida USA
Signature: 	Date: 30 JAN 2020

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Complete Listing of Reference Numbers

Treovance Abdominal Stent-Graft with Navitel delivery System

#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN	#	REFERENCE NO.	GTIN
1	28-B1-20-080S	08436045394385	34	28-L1-10-140S	08436045394255	67	28-C1-22-055S	08436045394712
2	28-B1-20-100S	08436045394460	35	28-L1-10-160S	08436045394323	68	28-C1-22-070S	08436045394798
3	28-B1-20-120S	08436045394545	36	28-L1-10-180S	08436045394088	69	28-C1-24-040S	08436045394644
4	28-B1-22-080S	08436045394392	37	28-L1-12-080S	08436045394057	70	28-C1-24-055S	08436045394729
5	28-B1-22-100S	08436045394477	38	28-L1-12-100S	08436045394125	71	28-C1-24-070S	08436045394804
6	28-B1-22-120S	08436045394552	39	28-L1-12-120S	08436045394194	72	28-C1-26-040S	08436045394651
7	28-B1-24-080S	08436045394408	40	28-L1-12-140S	08436045394262	73	28-C1-26-055S	08436045394736
8	28-B1-24-100S	08436045394484	41	28-L1-12-160S	08436045394330	74	28-C1-26-070S	08436045394811
9	28-B1-24-120S	08436045394569	42	28-L1-12-180S	08436045394095	75	28-C1-28-040S	08436045394668
10	28-B1-26-080S	08436045394415	43	28-L1-14-080S	08436045394064	76	28-C1-28-055S	08436045394743
11	28-B1-26-100S	08436045394491	44	28-L1-14-100S	08436045394132	77	28-C1-28-070S	08436045394828
12	28-B1-26-120S	08436045394576	45	28-L1-14-120S	08436045394200	78	28-C1-30-040S	08436045394675
13	28-B1-28-080S	08436045394422	46	28-L1-14-140S	08436045394279	79	28-C1-30-055S	08436045394750
14	28-B1-28-100S	08436045394507	47	28-L1-14-160S	08436045394347	80	28-C1-30-070S	08436045394835
15	28-B1-28-120S	08436045394583	48	28-L1-17-100S	08436045394149	81	28-C1-33-040S	08436045394682
16	28-B1-30-080S	08436045394439	49	28-L1-17-120S	08436045394217	82	28-C1-33-055S	08436045394767
17	28-B1-30-100S	08436045394514	50	28-L1-17-140S	08436045394286	83	28-C1-33-070S	08436045394842
18	28-B1-30-120S	08436045394590	51	28-L1-17-160S	08436045394354	84	28-C1-36-040S	08436045394699
19	28-B1-33-080S	08436045394446	52	28-L1-20-100S	08436045394156	85	28-C1-36-055S	08436045394774
20	28-B1-33-100S	08436045394521	53	28-L1-20-120S	08436045394224	86	28-C1-36-070S	08436045394859
21	28-B1-33-120S	08436045394606	54	28-L1-20-140S	08436045394293			
22	28-B1-36-080S	08436045394453	55	28-L1-20-160S	08436045394361			
23	28-B1-36-100S	08436045394538	56	28-L1-24-100S	08436045394163			
24	28-B1-36-120S	08436045394613	57	28-L1-24-120S	08436045394231			
25	28-L1-08-080S	08436045394033	58	28-L1-24-140S	08436045394309			
26	28-L1-08-100S	08436045394101	59	28-L1-24-160S	08436045394378			
27	28-L1-08-120S	08436045394170	60	28-S1-08-080S	08436045394002			
28	28-L1-08-140S	08436045394248	61	28-S1-10-080S	08436045394019			
29	28-L1-08-160S	08436045394316	62	28-S1-12-080S	08436045394026			
30	28-L1-08-180S	08436045394071	63	28-C1-20-040S	08436045394620			
31	28-L1-10-080S	08436045394040	64	28-C1-20-055S	08436045394705			
32	28-L1-10-100S	08436045394118	65	28-C1-20-070S	08436045394781			
33	28-L1-10-120S	08436045394187	66	28-C1-22-040S	08436045394637			

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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			

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TREO AUI Stent-Graft System

#	REFERENCE NO.	GTIN
1	28-A1-20-100S	08436045397560
2	28-A1-22-100S	08436045397577
3	28-A1-24-100S	08436045397584
4	28-A1-26-100S	08436045397591
5	28-A1-28-100S	08436045397607
6	28-A1-30-100S	08436045397614
7	28-A1-33-100S	08436045397621
8	28-A1-36-100S	08436045397638

TREO Occluder System

#	REFERENCE NO.	GTIN
1	28-P1-08-031S	08436045397645
2	28-P1-10-031S	08436045397652
3	28-P1-12-031S	08436045397669
4	28-P1-14-033S	08436045397676
5	28-P1-17-033S	08436045397683
6	28-P1-20-035S	08436045397690
7	28-P1-24-035S	08436045397706