

FORMA

CP Nr.: 01484

PAVADINIMAS: Atitikties deklaracija – CE (MDD)	Dokumento Nr. Form-0105 Rev G
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ATITIKIMO DEKLARACIJA Bolton Medical, Inc.	
Gamintojo pavadinimas:	
Adresas:	799 International Parkway Saulėtekis, Florida 33325 JAV
Produkto pavadinimas:	<u>„Treovance“ / „TREO“ i renginių šeima:</u> Treovance Pilvo stento transplantatas su Navitel pristatymu Sistema TREO pilvo stento-transplantato sistema TREO AUI Stent-Graft sistema TREO Occluder sistema
Produktų kategorijos (pvz., vainikinių arterijų stentai, stento transplantatai):	Stentas-transplantatas
Indikacijos:	Infrarenalinės pilvo aortos aneurizmų gydymas suaugusiems pacientams.
Projektavimo / gamybos į renginiai:	Bolton Medical, Inc. 799 International Parkway Sunrise, Florida, 33325 JAV  Europos į galiotasis atstovas: Emergo Europe BV Prinsessegracht 20 2514 AP Haga Nyderlandai Visą
Modeliai / nuorodos (jei reikia, pridėkite sąrašą):	sąrašą žr. priede  28-B1-XX-XXXS, 28-L1-XX-XXXS, 28-C1-XX-XXXS 28-S1-XX-XXXS nuorodos: Treovance Pilvo stento transplantatas su Navitel pristatymu Sistema  28-B2-XX-XXXS, 28-L2-XX-XXXS, 28-C2-XX-XXXS, 28-S2-XX-XXXS nuorodos: TREO pilvo stento-transplantato sistema  28-A1-XX-XXXS nuorodos: TREO AUI Stent-Graft sistema  28-P1-XX-XXXS nuorodos: TREO Occluder sistema
Klasifikacija (MDD, IX priedas):	III klasė (pagal 8 taisyklę)

FORM

CP #: 01484

TITLE: Declaration of Conformity – CE (MDD)

Document # Form-0105 Rev G

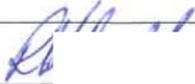
DECLARATION OF CONFORMITY	
Conformity Assessment Route:	Annex II, section 4 is applied for the Design Examination Certificate
Quality System Certificate Number:	CE 716356 (Full Quality Assurance System)
Issued By (Notified Body Name / Number / Address):	BSI Group The Netherlands B.V. (number 2797) BSI, 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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Pilnas nuorodų numerių sąrašas

Treovance pilvo stento transplantatas su Navitel į vedimo sistema

#	NJORODA NE.	GTIN	#	NJORODA NE.	GTIN	#	NJORODA NE.	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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## TREQ pilvo stento-transplantato sistema

# NUORODA NE.	GTIN	# NUORODA NE.	GTIN	# NUORODA NE.	GTIN
1 28-B2-20-080S 2	08436045396709	34 28-C2-26-040S 35	08436045396976	67 28-L2-15-140S 68	08436045397423
28-B2-20-100S 3 28-	08436045396785	28-C2-26-055S 36 28-	08436045397058	28-L2-15-160S 69 28-	08436045397492
B2-20-120S 4 28	08436045396860	C2-26-070S 37 28-	08436045397133	L2-17-080S 70 28-	08436045397225
-B2-22-080S 5 28-	08436045396716	C2-28-040S 38 28-	08436045396983	L2-17-100S 71 28-	08436045397294
B2-22-100S 6 28-	08436045396792	C2-28-055S 39 28	08436045397065	L2-17-120S 72 28	08436045397362
B2-22-1280	08436045396877	-C2-28-S8-28 -C2-30-040S	08436045397140	-L2-17-S817 -L2-17-160S	08436045397430
-B2-24-080S 8 28-	08436045396723	41 28-C2-30-055S 42	08436045396990	74 28-L2-20-080S 75	08436045397508
B2-24-100S 9 28-	08436045396808	28-C2-30-070S 43 28-	08436045397072	28-L2-20-100S 76 28-	08436045397232
B2-24-120S 10 28-	08436045396884	C2-33-040S 44 28-	08436045397157	L2-20-120S 77 28-	08436045397300
B2-26-080S 11 28-	08436045396730	C2-33-055S 45 28 -	08436045397003	L2-20-140S 78 28-	08436045397379
B2-26-100S 12 28-	08436045396815	C2-33-070S -36-040S	08436045397089	L2-20-160S 729-160S	08436045397447
B2-26-120S - B23	08436045396891	47 28-C2-36-055S 48	08436045397164	-24-080S 80 28-	08436045397515
-28-080S 14 28-	08436045396747	28-C2-36-070S 49 28-	08436045397010	L2-24-100S 81 28-	08436045397249
B2-28-100S 15 28-	08436045396822	L2-09-080S 50 28-	08436045397096	L2-24-120S 82 28-	08436045397317
B2-28-120S 16 28-	08436045396907	L2-09-100S 51 28-	08436045397171	L2-24-140S 83 28-	08436045397386
B2-30-080S 17 28-	08436045396754	L2-09-1280 - L520	08436045397188	L2-24-160S 84 28-	08436045397454
B2-30-100S 18 28-	08436045396839	-140S 53 28-	08436045397256	S2-09-080S -	08436045397522
B2-30-1280 - B2-33	08436045396914	L2-09-160S 54 28-	08436045397324	S82-1211 -080S 86	08436045397539
-080S 20 28-	08436045396761	L2-11-080S 55 28-	08436045397393	28-S2-13-080S	08436045397546
B2-33-100S 21 28-	08436045396846	L2-11-100S 56 28-	08436045397461		08436045397553
B2-33-120S 22 28-	08436045396921	L2-11-120S 57 28-	08436045397195		
B2-36-080S 23 28-	08436045396778	L2-11-140S 58 -S 21-1	08436045397263		
B2-36-100S 24 28-	08436045396853	59 28-L2-13-080S 60	08436045397331		
B2-36-120S 25-20-0	08436045396938	28-L2-13-100S 61 28-	08436045397409		
26 28-C2-20-055S 27	08436045396945	L2-13-120S 62 28	08436045397478		
28-C2-20-070S 28 28-	08436045397027	-L2-13-140S 63 28-	08436045397201		
C2-22-040S 29 28	08436045397102	L2-13-160S 64 28 -L2-	08436045397270		
-C2-22-055S 30 28-	08436045396952	S815 -L2-15-100S 66	08436045397348		
C2-22-070S 31 28 -C2-	08436045397034	28-L2-15-120S	08436045397416		
S824 -C2-24-055S 33	08436045397119		08436045397485		
28-C2-24-070S	08436045396969		08436045397218		
	08436045397041		08436045397287		
	08436045397126		08436045397355		

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## TREGO AUI Stent-Graft sistema

#	NUORODA NE. GTIN	
1	28-A1-20-100S 0843	6045397560
2	28-A1-22-100S 0843	6045397577
3	28-A1-24-100S 0843	6045397584
4	28-A1-26-100S 0843	6045397591
5	28-A1-28-100S 0843	6045397607
6	28-A1-30-100S 0843	6045397614
7	28-A1-33-100S 0843	6045397621
8	28-A1-36-100S 0843	6045397638

## TREGO Occluder sistema

#	NUORODA NE. 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