

CE - Declaration of Conformity



No.: 20 02 0123 A 010

We hereby declare that our products

Product:	Leads for Brady IPGs and their auxiliary components
Type:	Siello S, Siello T, Siello JT, Solia S, Solia T, Solia JT
Model:	see Attachment
EC-Class:	AIMD

are in conformance with the Design Dossier Documentation according to Annex 2, Section 4 of the Directive 90/385/EEC (AIMD) for which the EC-Design Examination Certificate

Certificate No.:	I7 010275 0521 Rev. 00
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Date of Issue:	June 11, 2019

has been issued.

To these products our certified Full Quality Assurance System according to Annex 2 of the Directive 90/385/EEC (AIMD) is applied. For this QA-system the certificate

Certificate No.:	I1 010275 0394 Rev. 01
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Date of Issue:	Oct. 18, 2019

has been issued.

These products meet the provisions of the Directive 90/385/EEC (AIMD) which apply to them. Any subsequent revisions or renewed versions of the QA-certificate are applicable to this declaration. This declaration is made under the full and sole responsibility of the Manufacturer BIOTRONIK SE & Co. KG.

BIOTRONIK SE & Co. KG
Woermannkehe 1
12359 Berlin, Germany

March 4, 2020


i.V. Axel Steiof
Director Regulatory Affairs



Attachment to
 Declaration of Conformity No.: 20 02 0123 A 010
 Page 1 of 1

Leads for Brady IPGs and their auxiliary components

Type	Model
Implantable, steroid eluting, bipolar active fixation bradycardia lead, 45/53/60 cm lead length, IS-1 connector, MR conditional	Siello S 45 Siello S 53 Siello S 60 Solia S 45 Solia S 53 Solia S 60
Stylet	S 45-K, S 53-K, S 60-K S 45-F, S 53-F, S 60-F S 45-J, S 53-J S 45-JL, S 53-JL
Lead Fixation Sleeve	EFH-6F; EFH-6F-W
Stylet Guide	SG-UP
Vein Lifter	VL-6
Fixation Tool	DH; DH IS-1/DF4

Type	Model
Implantable, steroid eluting, bipolar passive fixation bradycardia lead, 45/53/60 cm lead length, IS-1 connector, MR conditional	Siello JT 45 Siello JT 53 Siello T 53 Siello T 60 Solia JT 45 Solia JT 53 Solia T 53 Solia T 60
Stylet	S 45-K, S 53-K, S 60-K S 45-F, S 53-F, S 60-F
Lead Fixation Sleeve	EFH-6F; EFH-6F-W
Stylet Guide	SG-BP
Vein Lifter	VL-6

BIOTRONIK SE & Co. KG
 Woermannkehre 1
 12359 Berlin, Germany

March 4, 2020


 i.V. Axel Steiof
 Director Regulatory Affairs