



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 010275 0521 Rev. 00

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehre 1
12359 Berlin
GERMANY

Product:

Leads for Brady IPGs and their auxiliary components

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713146599

Valid from:

2019-06-11

Valid until:

2024-05-26

Date,

2019-06-11

Stefan Preiß



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 010275 0521 Rev. 00

Model(s): see below

Facility(ies): BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

Design Facility: BIOTRONIK SE & CO.KG
Woermannkehre 1, 12359 Berlin, GERMANY

Test Report No.: 71354710, 713050702, 713112367

Model:	Variants:
Siello S 45	Implantable, steroid eluting, bipolar active fixation bradycardia lead, 45cm lead length, IS-1 connector, MR conditional
Siello S 53	Implantable, steroid eluting, bipolar active fixation bradycardia lead, 53cm lead length, IS-1 connector, MR conditional
Siello S 60	Implantable, steroid eluting, bipolar active fixation bradycardia lead, 60cm lead length, IS-1 connector, MR conditional

Test Report No.: 71385156, 71374502, 713050174, 713112367

Model:	Variants:
Solia S 45	Implantable, steroid eluting, bipolar active fixation bradycardia lead, 45cm lead length, IS-1 connector, MR conditional
Solia S 53	Implantable, steroid eluting, bipolar active fixation bradycardia lead, 53cm lead length, IS-1 connector, MR conditional

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ **CERTIFICATE** ◆ **認證證書** ◆ **CERTIFICADO** ◆ **CERTIFICAT**



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)

(Other devices than custom made or intended for clinical investigation)

No. I7 010275 0521 Rev. 00

Solia S 60

Implantable, steroid eluting, bipolar active fixation bradycardia lead, 60cm lead length, IS-1 connector, MR conditional

Including the following accessories:

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

EFH-6F

EFH-6F-W

SG-UP

VL-6

DH; DH IS-1/DF4

Stylets

Lead Fixation Sleeve

White Lead Fixation Sleeve

Stylet Guide

Vein Lifter

Fixation Tool

Test Report No.: 71354710, 713050702, 713112367

Model:

Variants:

Siello JT 45

Implantable, steroid eluting, bipolar passive fixation bradycardia lead, 45cm lead length, IS-1 connector, MR conditional

Siello JT 53

Implantable, steroid eluting, bipolar passive fixation bradycardia lead, 53cm lead length, IS-1 connector, MR conditional

Siello T 53

Implantable, steroid eluting, bipolar passive fixation bradycardia lead, 53cm lead length, IS-1 connector, MR conditional

Siello T 60

Implantable, steroid eluting, bipolar passive fixation bradycardia lead, 60cm lead length, IS-1 connector, MR conditional

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

