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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
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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



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**Model(s):** see below

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

**Design Facility:** BIOTRONIK SE & CO.KG  
Woermannkehe 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



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**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



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

**No. I7 010275 0521 Rev. 00**

Test Report No.: 713029693, 713050174, 713112367

## Model:

## Variants:

Solia JT 45

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

Solia JT 53

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

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

## Model:

## Variants:

Solia T 53

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

Solia T 60

Implantable, steroid eluting, bipolar passive  
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  
EFH-6F  
EFH-6F-W  
SG-BP  
VL-6

Stylets  
Lead Fixation Sleeve  
White Lead Fixation Sleeve  
Stylet Guide  
Vein Lifter