



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 0522 Rev. 00

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehre 1

12359 Berlin

GERMANY

Product:

**Leads for Heart Failure Treatment and
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.:

713150811

Valid from:

2019-07-02

Valid until:

2024-05-26

Date,

2019-06-14

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.: 713036921

Model

Variants

Sentus OTW QP L-75

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR Conditional

Sentus OTW QP L-85

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR Conditional

Sentus OTW QP L-95

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR Conditional

Sentus ProMRI OTW QP L-75

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR Conditional

Sentus ProMRI OTW QP L-85

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR Conditional

Sentus ProMRI OTW QP L-95

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR Conditional



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No. I7 010275 0522 Rev. 00

Test Report No.: 713047124

Model:

Sentus OTW QP S-75

Sentus OTW QP S-85

Sentus OTW QP S-95

Sentus ProMRI OTW QP S-75

Sentus ProMRI OTW QP S-85

Sentus ProMRI OTW QP S-95

Variants:

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional

Test Report No.: 713096411

Model:

Sentus OTW QP L-75/49

Variants:

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional



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Sentus OTW QP L-85/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Sentus OTW QP L-95/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional

Sentus ProMRI OTW QP L-75/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional

Sentus ProMRI OTW QP L-85/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Sentus ProMRI OTW QP L-95/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional

Test Report No.: 713077335

Model:

Variants:

Sentus OTW QP S-75/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional

Sentus OTW QP S-85/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Sentus OTW QP S-95/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional



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Sentus ProMRI OTW QP S-75/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 77cm length,
IS4 connector, MR conditional

Sentus ProMRI OTW QP S-85/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 87cm length,
IS4 connector, MR conditional

Sentus ProMRI OTW QP S-95/49

Implantable, steroid eluting, quadripolar,
coronary sinus lead, 97cm length,
IS4 connector, MR conditional

Including the following accessories:

S 75-K OTW, S 85-K OTW, S 95-K OTW

Stylet

S 75-G OTW, S 85-G OTW, S 95-G OTW

Stylet

IS4/DF4-Adapter

Adapter

EFH-5F-W, EFH-20-5F

Lead Fixation Sleeve

VL-6

Vein Lifter