

CE - Declaration of Conformity



No.: 20 02 0123 A 009

We hereby declare that our products

Product:	Leads for Heart Failure Treatment and their auxiliary components
Type:	Sentus (ProMRI) OTW QP L-xx, Sentus (ProMRI) OTW QP S-xx, Sentus (ProMRI) OTW QP L-xx/49, Sentus (ProMRI) OTW QP S-xx/49
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 0522 Rev. 00
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Valid from:	July 2, 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
Valid from:	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
Woermannkehre 1
12359 Berlin, Germany

March 4, 2020

i.V. Axel Steiof
Director Regulatory Affairs



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Leads for Heart Failure Treatment and their auxiliary Components

Type	Model
Implantable, steroid eluting, quadripolar, coronary sinus lead, 77cm length, IS4 connector, MR conditional	Sentus OTW QP L-75
Implantable, steroid eluting, quadripolar, coronary sinus lead, 87cm length, IS4 connector, MR conditional	Sentus OTW QP L-85
Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus OTW QP L-95
Implantable, steroid eluting, quadripolar, coronary sinus lead, 77cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-75
Implantable, steroid eluting, quadripolar, coronary sinus lead, 87cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-85
Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-95
Including the following accessories:	
S 75-K OTW, S 85-K OTW, S 95-K OTW S 75-G OTW, S 85-G OTW, S 95-G OTW	Stylet
EFH-20-5F, EFH-5F-W	Lead fixation sleeve
VL-6	Vein Lifter
IS4/DF4-Adapter	Adapter

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Leads for Heart Failure Treatment and their auxiliary Components

Type	Model
Implantable, steroid eluting, quadripolar, coronary sinus lead, 77cm length, IS4 connector, MR conditional	Sentus OTW QP S-75
Implantable, steroid eluting, quadripolar, coronary sinus lead, 87cm length, IS4 connector, MR conditional	Sentus OTW QP S-85
Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus OTW QP S-95
Implantable, steroid eluting, quadripolar, coronary sinus lead, 77cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP S-75
Implantable, steroid eluting, quadripolar, coronary sinus lead, 87cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP S-85
Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP S-95
Including the following accessories:	
S 75-K OTW, S 85-K OTW, S 95-K OTW S 75-G OTW, S 85-G OTW, S 95-G OTW	Stylet
EFH-20-5F, EFH-5F-W	Lead fixation sleeve
VL-6	Vein Lifter
IS4/DF4-Adapter	Adapter

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Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus OTW QP L-95/49
Implantable, steroid eluting, quadripolar, coronary sinus lead, 77cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-75/49
Implantable, steroid eluting, quadripolar, coronary sinus lead, 87cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-85/49
Implantable, steroid eluting, quadripolar, coronary sinus lead, 97cm length, IS4 connector, MR conditional	Sentus ProMRI OTW QP L-95/49
Including the following accessories:	
S 75-K OTW, S 85-K OTW, S 95-K OTW S 75-G OTW, S 85-G OTW, S 95-G OTW	Stylet
EFH-20-5F, EFH-5F-W	Lead fixation sleeve
VL-6	Vein Lifter
IS4/DF4-Adapter	Adapter

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Leads for Heart Failure Treatment and their auxiliary Components

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S 75-K OTW, S 85-K OTW, S 95-K OTW S 75-G OTW, S 85-G OTW, S 95-G OTW	Stylet
EFH-20-5F, EFH-5F-W	Lead fixation sleeve
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