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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 0523 Rev. 00

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehre 1
12359 Berlin
GERMANY

Product:

Implantable Pacemakers

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.:

713153860

Valid from:

2019-11-07

Valid until:

2024-05-26

Date,

2019-11-07

Christoph Dicks

Head of Certification/Notified Body



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Model(s): see below

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

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

Products: **Implantable Pacemakers**

Test Report No.: 713079787, 713134395

Model	Variants	Catalogue Number:
Edora 8 DR	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional	407152
Edora 8 DR-T	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, Home Monitoring, MR conditional	407145
Edora 8 HF-T	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber, Rate Adaptive, unipolar / bipolar, IS-1 compatible, Home Monitoring, MR conditional	407138
Edora 8 HF-T QP	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, unipolar / bipolar, IS4 compatible, Home Monitoring, MR conditional	407137
Edora 8 SR	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional	407164
Edora 8 SR-T	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, Home Monitoring, MR conditional	407157



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Enitra 6 DR	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional	407153
Enitra 6 DR-T	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional	407150
Enitra 6 SR	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional	407165
Enitra 6 SR-T	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional	407162
Enitra 8 DR-T	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional	407147
Enitra 8 HF-T	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber, Rate Adaptive, unipolar / bipolar, IS-1 compatible, Home Monitoring, MR conditional	407142
Enitra 8 HF-T QP	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, unipolar / bipolar, IS4 compatible, Home Monitoring, MR conditional	407141
Enitra 8 SR-T	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional	407159
Enticos 4 D	Implantable Pacemaker, Dual Chamber, unipolar/bipolar, IS-1 Compatible, MR conditional	407156
Enticos 4 DR	Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional	407155



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Evity 8 HF-T	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber, Rate Adaptive, unipolar / bipolar, IS-1 compatible, Home Monitoring, MR conditional	407140
Evity 8 HF-T QP	Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, unipolar / bipolar, IS4 compatible, Home Monitoring, MR conditional	407139
Evity 8 SR-T	Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, Home Monitoring, MR conditional	407158