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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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|-------------------|---|--------|
| Enticos 4 S | Implantable Pacemaker, Single Chamber, unipolar/bipolar, IS-1 Compatible, MR conditional | 407168 |
| Enticos 4 SR | Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible, MR conditional | 407167 |
| Enticos 8 DR-T | Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring | 407148 |
| Enticos 8 HF-T | Implantable Pacemaker for Cardiac Resynchronization Therapy (CRT), Triple Chamber, Rate Adaptive, unipolar / bipolar, IS-1 compatible, Home Monitoring | 407144 |
| Enticos 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 | 407143 |
| Enticos 8 SR-T | Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring | 407160 |
| Evity 6 DR-T | Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional | 407149 |
| Evity 6 SR-T | Implantable Pacemaker, Single Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional | 407161 |
| Evity 8 DR-T | Implantable Pacemaker, Dual Chamber, Rate Adaptive, unipolar/bipolar, IS-1 Compatible , Home Monitoring, MR conditional | 407146 |



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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 |