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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

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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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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