



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 0513 Rev. 00

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehe 1
12359 Berlin
GERMANY

Product:

Implantable Cardioverter / Defibrillators

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.:

713140637

Valid from:

2019-06-11

Valid until:

2024-05-26

Date,

2019-06-11

I. Permit

Stefan Preiß

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Model(s): see below

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

Parameters:

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

Product: Implantable Cardioverter / Defibrillators

Test Report No.: 713071795

Model	Model No	Variant
Inlexa 3 VR-T	404703	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Inlexa 3 DR-T	404701	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Inlexa 3 HF-T	404699	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional



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Inlexa 3 HF-T QP	416037	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF-1 connector, MR conditional
Inlexa 3 VR-T	404704	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, DF4 connector, MR conditional
Inlexa 3 DR-T	404702	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4connector, MR conditional
Inlexa 3 HF-T	404700	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Inlexa 3 HF-T QP	416038	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional
Ilivia 7 VR-T	404625	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional



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Intica 7 VR-T	404634	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 5 VR-T	404689	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Ilivia 7 VR-T DX	404624	Implantable Cardioverter Defibrillators, single chamber with additional atrial detection, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 7 VR-T DX	404633	Implantable Cardioverter Defibrillators, single chamber with additional atrial detection, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 5 VR-T DX	404688	Implantable Cardioverter Defibrillators, single chamber with additional atrial detection, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Ilivia 7 DR-T	404622	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional



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Intica 7 DR-T	404631	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 5 DR-T	404686	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Ilivia 7 HF-T	404601 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Ilivia 7 HF-T	406035 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 7 HF-T	404627 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 7 HF-T	406039 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional
Intica 5 HF-T	404683	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF-1 connector, MR conditional



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Iliva 7 HF-T QP	404620 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF-1 connector, MR conditional
Intica 7 HF-T QP	404629 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF-1 connector, MR conditional
Intica 5 HF-T QP	406932	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF-1 connector, MR conditional
Ilivia 7 VR-T	404626	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, DF4 connector, MR conditional
Intica 7 VR-T	404635	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, DF4 connector, MR conditional



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Intica 5 VR-T	404690	Implantable Cardioverter Defibrillators, single chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, DF4 connector, MR conditional
Ilivia 7 DR-T	404623	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Intica 7 DR-T	404632	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Intica 5 DR-T	404687	Implantable Cardioverter Defibrillators, dual chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Ilivia 7 HF-T	404602 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Ilivia 7 HF-T	406036 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Intica 7 HF-T	404628 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional



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Intica 7 HF-T	406040 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Intica 5 HF-T	404684	Implantable Cardioverter Defibrillators, triple chamber, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/DF4 connector, MR conditional
Iliva 7 HF-T QP	404621 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional
Iliva 7 HF-T QP	406038 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional
Intica 7 HF-T QP	404630 (GB 2992)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional



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Intica 7 HF-T QP	406042 (LiS 3410RR)	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional
Intica 5 HF-T QP	404685	Implantable Cardioverter Defibrillators, triple chamber with IS4 port for connection of a quadripolar left ventricular lead, Rate Adaptive, Home Monitoring, max. shock energy: 40J, IS-1/IS4/DF4 connector, MR conditional