

# CE - Declaration of Conformity

No.:20 10 0123 A 031

We hereby declare that our products

Products:	Implantable Cardioverter / Defibrillators
Model:	See Attachment
EC-Class:	AIMD

are in conformance with the Design Dossier Documentation according to Annex II, Section 4 of the Directive 90/385/EEC (AIMD, OJ L 189) for which the EC-Design Examination Certificate

Certificate No.:	I7 010275 0513 Rev. 00
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Date of Issue:	June 11, 2019

has been issued.

To these products our certified Complete Quality Assurance System according to Annex II, Section 3 and 5 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
Date of Issue:	October 18, 2019

has been issued.

These products are also in conformance with the technical documentation according to Annex III , Module B of the Directive 2014/53/EC (RED, OJ L 153/62) for which the EU type examination certificate

Registration No.:	G0M-1612-6111-V02
Notified Body:	Eurofins Product Service GmbH, Storkower Strasse 38c, 15526 Reichenwalde b. Berlin, Germany
EEC No.:	0681
Date of Issue:	March 27, 2018

has been issued.

These products meet the provisions of the Directive 90/385/EEC and 2014/53/EC 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

October 22, 2020

  
i. V. Axel Steiof  
Director Regulatory Affairs



Attachment to  
Declaration of Conformity No.: 20 10 0123 A 031

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**Implantable Cardioverter/Defibrillators**

<b>Model</b>	<b>Catalogue Number</b>
Inlexa 3 VR-T	404703
Inlexa 3 DR-T	404701
Inlexa 3 HF-T	404699
Inlexa 3 HF-T QP	416037
Inlexa 3 VR-T	404704
Inlexa 3 DR-T	404702
Inlexa 3 HF-T	404700
Inlexa 3 HF-T QP	416038
Ilivia 7 VR-T	404625
Intica 7 VR-T	404634
Intica 5 VR-T	404689
Ilivia 7 VR-T DX	404624
Intica 7 VR-T DX	404633
Intica 5 VR-T DX	404688
Ilivia 7 DR-T	404622
Intica 7 DR-T	404631
Intica 5 DR-T	404686
Ilivia 7 HF-T	404601 (GB 2992)
Ilivia 7 HF-T	406035 (LiS 3410RR)
Intica 7 HF-T	404627 (GB 2992)
Intica 7 HF-T	406039 (LiS 3410RR)
Intica 5 HF-T	404683
Ilivia 7 HF-T QP	404620 (GB 2992)
Intica 7 HF-T QP	404629 (GB 2992)
Intica 5 HF-T QP	406932
Ilivia 7 VR-T	404626
Intica 7 VR-T	404635
Intica 5 VR-T	404690
Ilivia 7 DR-T	404623
Intica 7 DR-T	404632
Intica 5 DR-T	404687
Ilivia 7 HF-T	404602 (GB 2992)
Ilivia 7 HF-T	406036 (LiS 3410RR)
Intica 7 HF-T	404628 (GB 2992)
Intica 7 HF-T	406040 (LiS 3410RR)
Intica 5 HF-T	404684
Ilivia 7 HF-T QP	404621 (GB 2992)
Ilivia 7 HF-T QP	406038 (LiS 3410RR)
Intica 7 HF-T QP	404630 (GB 2992)
Intica 7 HF-T QP	406042 (LiS 3410RR)
Intica 5 HF-T QP	404685

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**Applied standards acc. to directive 2014/53/EU (RED)**

3.1a	EN 62479:2010	
3.1b	EN 301 489-1	V2.1.1:2017-02
	EN 301 489-27	V2.1.1:2016-12
	EN 301 489-31	V2.1.1:2016-11
3.2	EN 301 839	V2.1.1:2016-04
	EN 302 195	V2.1.1:2016-06

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