BIOTRONIK
excellence for life

CE - Declaration of Conformity

No.: 20 02 0123 A 001

We hereby declare that our products

Products:	Implantable Pacemakers
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 0523, Rev.00
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.	0123
Date of Issue:	November 7, 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-1611-6052-V01
Notified Body:	Eurofins Product Service GmbH, Storkower Strasse 38c, 15526 Reichenwalde b. Berlin, Germany
EEC No.:	0681
Date of Issue:	April 11, 2017

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

February 21,2020

i. V. Axel Steiof
Director Regulatory Affairs

Declaration of Conformity · Declaration of Conformity

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Attachment to
Declaration of Conformity No.: 20 02 0123 *A 001*

Implantable Pacemakers

Model	Catalogue Number
Edora 8 SR	407164
Enitra 6 SR	407165
Edora 8 DR	407152
Enitra 6 DR	407153
Edora 8 SR-T	407157
Evity 8 SR-T	407158
Enitra 8 SR-T	407159
Evity 6 SR-T	407161
Enitra 6 SR-T	407162
Edora 8 DR-T	407145
Evity 8 DR-T	407146
Enitra 8 DR-T	407147
Evity 6 DR-T	407149
Enitra 6 DR-T	407150
Edora 8 HF-T	407138
Evity 8 HF-T	407140
Enitra 8 HF-T	407142
Edora 8 HF-T QP	407137
Evity 8 HF-T QP	407139
Enitra 8 HF-T QP	407141
Enticos 4 S	407168
Enticos 4 D	407156
Enticos 4 SR	407167
Enticos 4 DR	407155
Enticos 8 SR-T	407160
Enticos 8 DR-T	407148
Enticos 8 HF-T	407144
Enticos 8 HF-T QP	407143

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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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