CE - Declaration of Conformity

BIOTRONIK
excellence for life

No. : 20 03 0123 A 012

We hereby declare that our products

Products:	Implantable Cardiac Monitoring and Recording Systems
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 0518, Rev.01
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.	0123
Date of Issue:	March 18, 2020

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. 00
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-1809-7676-V02
Notified Body:	Eurofins Product Service GmbH, Storkower Strasse 38c, 15526 Reichenwalde b. Berlin, Germany
EEC No.:	0681
Date of Issue:	November 25, 2019

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

March 19, 2020

i. V. Axel Steiof
Director Regulatory Affairs

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Attachment to Declaration of Conformity No.: 20 03 0123 *A 012*

Implantable Cardiac Monitoring and Recording Systems

Model	Catalogue Number
BIOMONITOR III	436066
BIOMONITOR IIIm	450218

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

3.1a	EN 62479:2010	
3.1b	EN 301 489-1	V2.2.0:2017-03
	EN 301 489-27	V2.2.1:2019-04
	EN 301 489-31	V2.2.1:2019-04
3.2	EN 301 839	V2.1.1:2016-04
	EN 302 195	V2.1.1:2016-06

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March 19, 2020

i. V. Axel Steiof
Director Regulatory Affairs

CE - Declaration of Conformity

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No.: 20 03 0123 A 013

We hereby declare that our products

Products:	User Device
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 0518, Rev. 01
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.	0123
Date of Issue:	March 18, 2020

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.00
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-1612-6101-V02
Notified Body:	Eurofins Product Service GmbH, Storkower Strasse 38c, 15526 Reichenwalde b. Berlin, Germany
EEC No.:	0681
Date of Issue:	January 31, 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.

In addition, BIOTRONIK SE & Co. KG declares that these products are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous subtances in electrical and electronic equipment.

BIOTRONIK SE & Co. KG
Woermannkehre 1
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March 19, 2020

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Director Regulatroy Affairs

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Attachment to
Declaration of Conformity No.: 20 03 0123 *A 013*

User Device

Model	**Catalogue Number**
Remote Assistant III	435292

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

3.1a	EN 45502-1:1997	
	EN 60601-1:2006+A12:2014	
	EN 62311:2008	
3.1b	EN 301 489-1	V2.2.0:2017-03
	EN 301 489-27	V2.2.0:2017-03
	EN 301 489-31	V2.2.0:2017-03
3.2	EN 301 839	V2.1.1:2016-04
	EN 302 195	V2.1.1:2016-06

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March 19, 2020

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