EU Declaration of Conformity

BIOTRONIK
excellence for life

No. 25 02 0123 RN 003

We hereby declare that our products are in compliance with the provisions of the following European Union (EU) directives at the time of this declaration.

Product	Telemonitoring System
Model	See attachment
Risk class	III
SRN	DE-MF-000005049
Intended purpose	See attachment

For these products, the EU technical documentation assessment certificate has been issued in compliance with Regulation (EU) 2017/745 (MDR) of the European Parliament and of the Council of April 5, 2017.

Certificate no.	G70 010275 0550 Rev. 00
Notified body	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich,
Germany EEC no.	0123
Valid from	2023-03-06

To these products our complete quality management (QM) system according to Annex IX, Chapters I and III, of the Regulation (EU) 2017/745 (MDR) is applied. The corresponding QM system certificate has been issued.

Certificate no.	G12 010275 0533 Rev. 10
Notified body	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich,
Germany EEC no.	0123
Valid from	2024-09-16

These products are also in conformance with the technical documentation according to Annex II, Module A of the Directive 2014/53/EC (RED, OJ L 153/62) of the European Parliament and of the Council of April 16, 2014.

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 June 8, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Any subsequent revisions or renewed versions of the QM 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

Berlin, 2025-02-26

i. V. Axel Steiof
Director Regulatory Affairs

Attachment to Declaration of Conformity

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No. 25 02 0123 RN 003

Products

Model	Basic UDI-DI
CardioMessenger Smart 4G	4035479BUDI00051Q3

GlobTek GTM96180 XX*
FRIWO FW8000/05 XX*

*XX: Country Code

Intended Purpose

The CardioMessenger Smart is a data transmitter. The use of the CardioMessenger Smart is necessary for a patient who carries a BIOTRONIK implantable device with Home Monitoring function to receive medical care via telemedicine. The CardioMessenger Smart is a part of the telemetry chain of the BIOTRONIK Home Monitoring System. It relays data between the implanted device and the Home Monitoring Service Center. The CardioMessenger Smart receives data from the implant and transmits it to the BIOTRONIK Home Monitoring Service Center via the GSM network. The CardioMessenger Smart is classified as an accessory of the implanted device and has no diagnostic or therapeutic function itself.

Applied standards according to directive 2014/53/EU (RED)

Art. 3.1 a	Health	EN 50566:2017	
	Safety	IEC 60601-1:2005/AMD2:2020	
Art. 3.1 b	EMC	EN 301 489-1	V2.1.1:2017-02
			V2.2.0:2017-03
			V2.2.3:2019-11
		EN 301 489-27	V2.2.1:2016-12
		EN 301 489-52	V1.2.1:2021-11
Art. 3.2	RF spectrum	EN 301 511	V12.5.1:2017-03
		EN 301 839	V2.1.1:2016-04
		EN 301 908-1	V15.2.1:2023-01
		EN 301 908-13	V13.2.1:2022-02

Common Specifications

Not applicable

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