ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03

Product Service

# 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 0518 Rev. 01**

**Manufacturer:** **BIOTRONIK SE & Co. KG**
Woermannkehre 1
12359 Berlin
GERMANY

**Product:** **Implantable Cardiac Monitoring and Recording Systems**

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.:** 713175304

**Valid from:** 2020-03-18
**Valid until:** 2024-05-26

**Date,** 2020-03-18

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**No. I7 010275 0518 Rev. 01**

| | |
|---|---|
| **Model(s):** | **BIOMONITOR III**<br>**BIOMONITOR IIIm** |
| **Product:** | **Implantable Cardiac Monitoring and Recording Systems** |
| Test Report No.: | 713155922 / 713175304 |

| **Model:** | **Variants:** |
|---|---|
| BIOMONITOR III | Implantable Cardiac Monitor with automatic recording of cardiac arrhythmias, recording of patient activated episodes, Home Monitoring®, silicone coating, MR conditional, with AF diagnostics, with accessories 'Incision Tool' and 'FIT OneStep' tool, 'BIOMONITOR III' implant premounted in 'FIT One Step' insertion tool |
| BIOMONITOR IIIm | Implantable Cardiac Monitor with automatic recording of cardiac arrhythmias, recording of patient activated episodes, Home Monitoring®, silicone coating, MR conditional, with AF diagnostics, with accessories 'Incision Tool' and 'FIT OneStep' tool, 'BIOMONITOR IIIm' implant premounted in 'FIT One Step' insertion tool |
| Remote Assistant III | User-trigger device |


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