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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010275 0528 Rev. 00

Manufacturer:

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
GERMANY

Product Category(ies): **Antibradycardia and Electrophysiological Devices (see page 2)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713163699

Valid from: 2020-05-12
Valid until: 2024-05-26

Date, 2020-05-12

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010275 0528 Rev. 00

Products / Product Categories:

I. ANTIBRADYCARDIA DEVICES

1. External pacemakers

II. ELECTROPHYSIOLOGY

1. Medical devices for electrophysiological applications incl. accessories
2. Ablation generators incl. accessories

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

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Manufacturer's Declaration in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	BIOTRONIK SE & Co KG
Manufacturer address and contact details	Woermannkehre 1, 12359 Berlin
Single Registration Number (SRN) (if available)	DE-MF-000005049

Authorised Representative name (if applicable)	n.a.
Authorised Representative address and contact details	n.a.
Single Registration Number (SRN) (if available)	n.a.

Notified body name (if applicable)	DNV MEDCERT GmbH ☐ See attached schedule
Notified body number (if applicable)	0482 ☐ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☑ Expired/expires *after* 20 March 2023

  Choose one applicable statement:

  ☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☑ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

BIOTRONIK SE & Co KG
Woermannkehre 1, 12359 Berlin

Berlin, 22 May 2024

Dr. Andreas Brandmair,
Team Manager Regulatory Affairs
andreas.brandmair@biotronik.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Reocor S, Model No: 365528	G1 010275 0528 Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH; 0123	DNV MEDCERT GmbH; 0482	2027-12-31	n.a.
Reocor D, Model No: 365529	G1 010275 0528 Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH; 0123	DNV MEDCERT GmbH; 0482	2027-12-31	n.a.
Qubic Stim - EP Heart Stimulator, Model No: 396165	G1 010275 0528 Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH; 0123	DNV MEDCERT GmbH; 0482	2027-12-31	n.a.
Qubic RF - RF Ablation Generator, Model No: 396166	G1 010275 0528 Rev. 00	2024-05-26	TÜV SÜD Product Service GmbH; 0123	DNV MEDCERT GmbH; 0482	2027-12-31	n.a.

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
20363GB448240117	20363AU01F	2024-01-17	2027-09-29

This is to certify that the quality system of

BIOTRONIK SE & Co. KG

Woermannkehre 1, 12359 Berlin, Germany

SRN: DE-MF-000005049

For design, production, and final product inspection/testing of

Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-01-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-info@dnv.com

Certificate no.: 20363GB448240117
Place and date: Hamburg, 2024-01-17

Sites covered by this certificate

BIOTRONIK SE & Co. KG, Woermannkehre 1, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Woermannkehre 2, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Ballinstrasse 16-18, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Ballinstrasse 20, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Sieversufer 7-9, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Buschkrugallee 33, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Buschkrugallee 27, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Buschkrugallee 21a, 12359 Berlin, Germany
BIOTRONIK SE & Co. KG, Buschkrugallee 21b, 12359 Berlin, Germany
BIOTRONIK Corporate Services SE, Sieversufer 7-9, 12359 Berlin, Germany

Products covered by this certificate

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

For class I medical devices with a measuring function (class Im), the audit of the quality management system was limited to the aspects relating to the conformity of the devices with the metrological requirements.

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Class	Medical devices/groups of medical devices
MDN 1203	Is	Lead delivery system

Class IIb medical devices, excluding implantable non-WET[i]

Category	EMDN code	Medical devices/groups of medical devices
MDA 0305	Z120507	CARDIOGRAPHY INSTRUMENTS

Intended purpose

The Qubic Stim system consists of a control unit and a stimulation unit. It is an active, non invasive medical device, which provides electrical stimulation patterns. It is used for the stimulation of the heart during an electrophysiological study (EPS) in the cardiac catheter laboratory, if used in combination with diagnostic catheters.

The intended purpose of the Qubic Stim is achieved by the following functions:

- Providing the electrical stimulation patterns “Programmed electrical stimulation” (PES) and “High rate stimulation" (burst)
- Measuring the sinus node recovery time (SNRT)
- Controlling all parameters of the operation of the device via the Control Unit

The Qubic Stim is not intended for permanent and unmonitored use as an external pacemaker.

Class III medical devices

For placing on the market of class III medical devices covered by this certificate, an additional EU Technical Documentation Assessment Certificate according to Annex IX Chapter II of Regulation (EU) 2017/745 is required, which also contains the exact determination of medical devices covered by certification.

Category	Medical devices/groups of medical devices
MDN 1203	Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools

[i] WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.