

Prot. n. 266/19/CRM/sz

Vimodrone, 25 Marzo 2019

Spettabile
S.C.R. Piemonte S.p.A.
Corso Marconi n. 10
10125 TORINO

OGGETTO: Gara Regionale Centralizzata per la stipula di un accordo quadro per la fornitura di pacemaker e servizi connessi per le aziende del servizio sanitario della regione Piemonte. Gara n. 10-2019

La scrivente società BIOTRONIK Italia S.p.A. con sede legale ed operativa in Vimodrone (MI), Via delle Industrie n. 11, (cap 20090) - Tel. 02/274394200-Fax 02/274394304 - C.F. e P.I. 09699320017 - Socio Unico BIOTRONIK International Vertriebs AG CH-6341 Baar (ZG) - in persona dell'Amministratore Delegato/Legale Rappresentante, Luca Torchi, nato a Genova il 13-07-1961 e residente a Varese in Via C. Bossi n. 6 - cod. fisc. TRCLCU61L13D969V

DICHIARA che:

BIOTRONIK ITALIA S.p.A., in caso di aggiudicazione, si impegna a consegnare in comodato d'uso (regolarizzato da debito contratto) il programmatore necessario per interrogare e programmare in modo non invasivo tutti i modelli di defibrillatori impiantati e tale apparecchiatura è debitamente coperta dalle norme di sicurezza IEC 60601. Verranno quindi forniti a titolo gratuito gli accessori necessari al suo utilizzo (testa telemetrica, cavo ECG, carta per programmatore, magneti, ecc.).

Il suddetto sistema di programmazione e controllo è messo a disposizione del Reparto utilizzatore per una durata non inferiore alla vita degli stimolatori cardiaci oggetto della fornitura e, durante tale periodo la manutenzione è totalmente a carico di BIOTRONIK ITALIA S.p.A.

Letto, confermato e sottoscritto.

BIOTRONIK ITALIA S.p.A.
Amministratore Delegato
Luca Torchi
Firmato Digitalmente

CRM

Cardiac Rhythm Management

Sistema di Programmazione

Renamic

Renamic

Sistema di Programmazione e Controllo dei dispositivi impiantabili

Monitor e registratore ECG, IEGM e marker

Dimensioni e Peso Ridotti

Intuitiva e chiara interfaccia software

Follow-up Guidato



Nr d'ordine 365533

Produttore: Biotronik SE & Co. KG, Berlino Germania

Codice CND: J01900203

Nr Repertorio: 447364

Questo prodotto è conforme alle direttive 90/385/CEE relativa ai dispositivi e accessori medici attivi impiantabili e 99/5/EC sulle apparecchiature radio e apparecchiature terminali di telecomunicazione. E' stato omologato da un ufficio indipendente ed è munito della marcatura CE

Renamic alsa 14112012.doc rev.1 14/11/121 et

BIOTRONIK
excellence for life

20090 Vimodrone (Mi)
Via Delle Industrie, 11
Tel. 02-274394.200 Fax. 02-274394.300
www.biotronik.com
info@biotronik.it

RENAMIC Dati Tecnici

Cassa

Dimensioni (LxAxP) ¹⁾	47,6 x 34,5 x 12,5 cm
Peso ²⁾	10, 5 kg
Schermo Display	retrattile, regolabile in inclinazione
Schermo	TouchScreen di ampie dimensioni
Ingressi/uscite	>tre porte USB
	stampante esterna; chiavetta di memoria; hard disk
	esterno; adattatore VGA; mouse
	> 2 connettori per cavi
	cavo ECG, testa di programmazione

Stampante

Stampante interna	> tipo di stampante	stampante termica per stampa ECG in tempo reale
	> formato carta, numero di fogli	11,2 x 12,5 cm, 210
Stampante esterna		tramite Bluetooth® ³⁾ o USB

Interrogazione dispositivo

Testa di programmazione	> dimensioni (L x A x P)	14,5 x 9,7 x 4,2 cm
	> lunghezza cavo	2,97 m
Telemetria RF senza testa telemetrica ⁴⁾		BIOTRONIK SafeSync®

Funzionalità del PC

Sistema operativo	Windows XP incorporato
Hard disk interno	min. 40 GB
Funzionalità	Possibilità di programmare i parametri di interesse (lingua, ora, data, ...)

Informazioni per l'ordine

Accessori standard inclusi con Renamic		371960
Accessori	> testa di programmazione	371588
	> cavo di alimentazione	specifico per ogni paese
	> penna	371 586
	> cavo ECG (PK 122)	specifico per ogni paese
	> clip elettrodo ECG	340 293
	> carta per stampante6)	348 728
	> chiavetta USB Bluetooth®	367 929
	> adattatore VGA	377 292
	> fascia per la spalla	371 962
	> chiusura di protezione	376 999
> adattatore seriale (RS-232)	376 437	

- 1) Sono inclusi due vani per il cavo di alimentazione, il cavo ECG e la testa di programmazione
- 2) Sono inclusi cavo di alimentazione, cavo ECG, stilo e testa di programmazione
- 3) Porta USB aggiuntiva per chiavetta Bluetooth®
- 4) Per i dispositivi impiantabili che supportano la telemetria senza testa telemetrica
- 5) Fare riferimento al manuale per il numero d'ordine
- 6) Due blocchi di carta per stampante nel kit di avvio

Nr d'ordine 365533

Produttore: Biotronik SE & Co. KG, Berlino Germania
 Codice CND: J01900203
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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. 17 15 08 10275 373

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehre 1
12359 Berlin
GERMANY

Product:

**Programmiers for Cardiac Implantable
Devices and their external components**

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.:

713063866

Valid from:

2015-09-23

Valid until:

2020-09-22



Date, 2015-08-14

Hans-Heiner Junker

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

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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. 17 15 08 10275 373**Model(s):** see attachment**Parameters:** ./.**Facility(ies):** BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY**Design
Facility(ies):** BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY



Product Service

Attachment for Certificate no I7 15 08 10275 373
dated 2015-08-14

Product: Programmers for Cardiac Implantable Devices
and their external components

Test Report No.: 71371465

Model:

Renamic	External Programmer
Renamic PGH	External Programmer, Programming Head
NK-xx*	Mains Power Cord
PK-222	Patient Cable
PK Electrode Clip	Adapter for Adhesives Electrodes

(*: country code)

Test Report No.: 71398531

Model:

Renamic PSA Module	Pacing System Analyzer Module
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Munich, CRT2, 2015-08-14

Hans-Heiner Junker
Certification Medical Technology

CE - Declaration of Conformity

No.: 17 06 0123 A 013

We hereby declare that our products

Products:	Programmers for Cardiac Implantable Devices and their external components
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 15 08 10275 373
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Date of Issue:	September 23, 2015

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 16 09 10275 394
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Date of Issue:	October 26, 2016

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-1704-6243-V01
Notified Body:	Eurofins Product Service GmbH, Storkower Strasse 38c, 15526 Reichenwalde b. Berlin, Germany
EEC No.:	0681
Date of Issue:	May 19, 2017

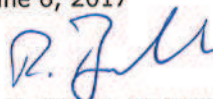
has been issued.

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.

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 substances in electrical and electronic equipment.

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany

June 6, 2017



i. V. Roman Borkowski
Vice President Global Regulatory Affairs
Medical Device Safety Officer



Attachment to
Declaration of Conformity No.: 17 06 0123 A 013

Programmers for Cardiac Implantable Devices and their external components

Model	Catalogue Number
Renamic	371960
Renamic PGH	371588
NK-xx*	
PK-222	335284
PK Electrode Clip	340293
Renamic PSA Module	386610

(*XX: Country Code)

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

3.1a	EN 62311:2008 EN 62479:2010	
3.1b	EN 301 489-1 EN 301 489-27 EN 301 489-31 EN 301 489-52	V2.1.1:2017-02 V2.1.1:2016-12 V2.1.1:2016-11 V1.1.0:2016-11
3.2	EN 301 839 EN 301 511 EN 301 908-1 EN 301-908-2 EN 302 195	V2.1.1:2016-04 V9.0.2:2013-03 V11.1.1:2016-07 V11.1.1:2016-07 V2.1.1:2016-06

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin, Germany

June 6, 2017


i. V. Roman Borkowski
Vice President Global Regulatory Affairs
Medical Device Safety Officer



Product Service

EC Certificate

Full Quality Assurance System

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 16 09 10275 394

Manufacturer:

BIOTRONIK SE & Co. KG

Woermannkehre 1

12359 Berlin

GERMANY



Product:

**Active Implants
(see attachment)**

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 AIMDD Annex 2. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of the devices / device categories an additional Annex 2 (4) certificate is mandatory. See also notes overleaf.

Report No.:

713080958

Valid from:

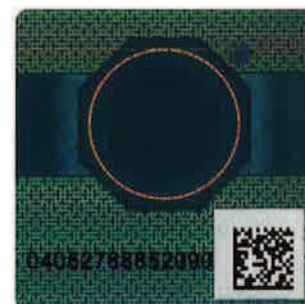
2016-10-26

Valid until:

2021-10-25

Date, 2016-08-18

Stefan Preiß



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

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Product Service

EC Certificate**Full Quality Assurance System**

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 excluding (4)
(Other devices than custom made or intended for clinical investigation)

No. I1 16 09 10275 394**Facility(ies):**

BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Ballinstrasse 20, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Ballinstrasse 16-18, 12359 Berlin, GERMANY

**Design
Facility(ies):**

BIOTRONIK SE & Co. KG
Woermannkehre 1, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Woermannkehre 2, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Buschkrugallee 21a, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Buschkrugallee 21b, 12359 Berlin, GERMANY

BIOTRONIK SE & Co. KG
Sieversufer 7-9, 12359 Berlin, GERMANY



Product Service

Attachment for Certificate no I1 16 09 10275 394
dated 2016-10-26

Products / Product Categories:

I. ANTIBRADYCARDIA DEVICES

1. Implantable pacemakers incl. accessories
2. Implantable leads with / without drug component incl. accessories
3. Programmers and measuring devices for implantable pacemakers
4. External threshold analyzer
5. External monitors for pacemaker

II. ANTITACHYCARDIA DEVICES

1. Implantable cardioverter / defibrillators incl. accessories
2. Implantable leads with / without drug component incl. accessories
3. Devices for the intraoperative application and follow-up incl. accessories
4. Programmers and measuring devices for implantable cardioverter / defibrillators incl. accessories

III. MEDICAL TELEMONITORING SYSTEMS

1. Active implantable devices incl. accessories
2. Receivers and transmitters incl. accessories
3. Service center incl. accessories

IV. ACTIVE IMPLANTABLE DIAGNOSTIC DEVICES

1. Implantable cardiac monitoring and recording systems

Munich, CRT2, 2016-08-18

Stefan Preiß
 Certification Medical Technology