Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: "Life MED" SRL , cu sediul *mun. Chişinău, Republica Moldova*

str. Tudor Strişcă, 30,declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

1) Cardioverter-defibrilator Implantabil Rivacor

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia *Semnătura* _____

Administrator Railean Efimia *Data* 21.09.2023

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIŞINĂU

Anexă nr 1

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 82 din 21 septembrie 2023

Solicitantul **„Life Med"** SRL , cu sediul *mun. Chişinău, Republica Moldova str. Tudor Strişcă, 30*, tel./fax: 060807745, e-mail vlas.ion@lifemed.md , solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

1) Cardioverter-defibrilator Implantabil Rivacor;

Se anexează următoarele acte:
DC 23 08 0123 RN 016 in numar de 3 pagini, MDR G70 010275 0544 Rev. 00 in numar de 4 pagini, Quality Management System G12 010275 0533 Rev. 09 in numar de 4 pagini,

Data 21 septembrie

Semnătura

Tabelul de recepţionare a notificării

(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

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BIOTRONIK SE & Co. KG • Postfach 470255 • 12311 Berlin

TO WHOM IT MAY CONCERN

BIOTRONIK SE & Co. KG
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 68905-1965
www.biotronik.com

CIS / 2022_492
www.biotronik.com

Berlin, 1. Dezember 2022

Tender №1663342194003

Letter of Authorization
Agentia Medicamentului și Dispozitivelor Medicale or. Chișinău, str. Korolenko 2/1, MD-2028

We, BIOTRONIK SE & Co. KG, Woermannkehre 1, 12359 Berlin, Germany, a manufacturer of implantable cardiac pacemakers, implantable cardioverters / defibrillators and products for the electrophysiology, having plants in Germany, hereby permit ***"LIFE MED" S.R.L., str. Doctor Tudor Strișcă, 30, mun. Chișinău, Republica Moldova***, related to the tender №1663342194003, to sell on its own behalf and on its own account all the products manufactured by us throughout the Republic of Moldova and therefore confirm that it can negotiate and conclude respective contracts on its own behalf and on its own account with regard to such products.

We hereby confirm that the guarantee related to our products also extends to the company LIFE MED S.R.L..

Furthermore, we hereby authorize LIFE MED S.R.L. to record in registers, notify, renew or modify the registration of medical products (implantable cardiac pacemakers, implantable cardioverters/defibrillators, implantable cardiac monitors, ablation and diagnostic catheters, peel-away introducers) with the competent health authorities in the territory of the Republic of Moldova. In case of a products registration in the name of LIFE MED S.R.L., we reserve the right to transfer the product registration to our name and/or make changes to the registration at any time as we deem necessary.

This Letter of Authorization is valid until 31st December 2023.

BIOTRONIK SE & Co. KG

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

DocuSigned by:
Udo Tegtmeyer
CD0EC69766E14BC...

p.p. Udo Tegtmeyer
Vice President CENEMEA

BIOTRONIK
excellence for life
BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin

DocuSigned by:
Katrin Mayr-Baxmann
895E1F11AC054F9...

Katrin Mayr-Baxmann
Senior Legal Counsel

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CE - Declaration of Conformity

No.: 23 08 0123 RN 016

We hereby declare that our products

Products:	*Implantable Cardioverter / Defibrillators*
Model:	*See Attachment*
Risk-Class:	*III*
SRN Number:	*DE-MF-000005049*
Intended purpose:	*See Attachment*

are in conformance with the Technical Documentation according to Annex IX, Chapter II, of the Regulation (EU) 2017/745 (MDR) for which the EU Technical Documentation Assessment Certificate

Certificate No.:	*G70 010275 0544 Rev. 00*
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.	0123
Valid from:	*February 09, 2023*

has been issued.

To these products our certified Quality Management System according to Annex IX, Chapters I and III, of the Regulation (EU) 2017/745 (MDR) is applied. For this QM-system the certificate

Certificate No.:	G12 010275 0533 Rev. 09
Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany
EEC No.:	0123
Valid from:	*June 28, 2023*

has been issued.

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).

These products meet the provisions of the Regulation (EU) 2017/745 (MDR) of the European Parliament and of the Council of 5 April 2017 and 2014/53/EC of the European Parliament and of the Council of 16. April 2014 which apply to them.

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

August 24, 2023

i. V. Axel Steiof
Director Regulatory Affairs

«LIFE MED» S.R.L. IDNO 1014600035666 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA, mun. CHIȘINĂU

Declaration of Conformity · Declaration of Conformity ·

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Attachment to Declaration of Conformity No.: 23 08 0123 RN 016

I. Products

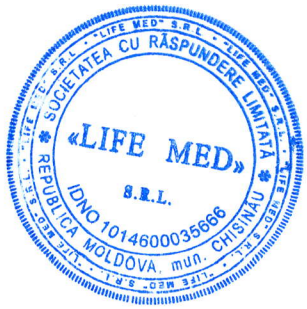
Model	Basic UDI-DI
Acticor 7 VR-T Rivacor 7 VR-T Rivacor 5 VR-T Rivacor 3 VR-T Acticor 7 VR-T DX Rivacor 7 VR-T DX Rivacor 5 VR-T DX Acticor 7 DR-T Rivacor 7 DR-T Rivacor 5 DR-T Rivacor 3 DR-T	4035479BUDI00053Q7
Acticor 7 HF-T Rivacor 7 HF-T Rivacor 5 HF-T Rivacor 3 HF-T Acticor 7 HF-T QP Rivacor 7 HF-T QP Rivacor 5 HF-T QP Rivacor 3 HF-T QP	4035479BUDI00065QE

II. Intended purpose

Acticor, Rivacor are implantable cardioverter-defibrillators (ICDs: VR-T, VR-T DX and DR-T) and cardiac resynchronization therapy defibrillators (CRT-Ds: HF-T and HF-T QP).

An ICD/CRT-D is part of an implantable System comprising an implantable ICD/CRT-D and leads. The primary function of the ICD System is the ability, first, to sense and record the intrinsic heart rhythm/rate and, second, to provide antitachycardia pacing by electrical pulses of low energy or a shock by electrical pulses of high energy, as well as to provide pacing by electrical pulses of low energy to ensure a stable heart rate or to support the intrinsic heart rate. CRT Systems share all mentioned functions and in addition provide permanent sensing and pacing of the left ventricle.
The Implantation of an ICD/CRT-D is a symptomatic therapy with the following objectives:

- Sensing and recording the heart rhythm and automatically detecting cardiac arrest (ICDs and CRT-Ds).
- Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery(ICDs and CRT-Ds).
- Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds).
- Compensation of bradycardia through ventricular or AV sequential pacing (ICDs and CRT-Ds).
- Cardiac resynchronization through multisite ventricular pacing (CRT-Ds, e.g., biventricular pacing).



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Attachment to
Declaration of Conformity No.: 23 08 0123 RN 016

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

Art. 3.1a	Safety	ISO 14708-1:2014 ISO 14708-6:2010	
	Health	EN 62479:2010	
Art. 3.1b	EMC	EN 301 489-1 EN 301 489-27 EN 301 489-31	V2.2.0:2017-03 V2.2.1:2019-04 V2.2.1:2019-04
Art. 3.2	Radio	EN 301 839 EN 302 195	V2.1.1:2016-04 V2.1.1:2016-06

IV. Common Specifications

Not applicable

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

August 24, 2023

i. V. Axel Steiof
Director Regulatory Affairs

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 010275 0533 Rev. 09

Manufacturer:

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin
GERMANY

SRN Manufacturer - DE-MF-000005049

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G12 010275 0533 Rev. 09

Report No.: 713277927

Preceding Certificate No.: G12 010275 0533 Rev. 08

Valid from: 2023-06-28
Valid until: 2024-09-16

Date of Initial Issuance: 2019-09-17

«LIFE MED» S.R.L. IDNO 1014600035666 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA, mun. CHIȘINĂU

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-06-28

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

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 010275 0533 Rev. 09

Classification:	Class III
Device Group:	J019002 - IMPLANTABLE CARDIAC DEVICES PROGRAMMERS AND ACCESSORIES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010792 - ACTIVE IMPLANTABLE CARDIAC DEVICES REMOTE MONITORING SYSTEMS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-
Classification:	Class III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	Class III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	Class III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Intended Purpose:	-
Classification:	Class III
Device Group:	J010101 - IMPLANTABLE SINGLE CHAMBER PACEMAKERS
Intended Purpose:	-
Classification:	Class III
Device Group:	J010103 - IMPLANTABLE DUAL CHAMBER PACEMAKERS
Intended Purpose:	-
Classification:	Class III
Device Group:	J010104 - IMPLANTABLE TRIPLE CHAMBER PACEMAKERS
Intended Purpose:	-
Classification:	Class III
Device Group:	J019001 - PERMANENT CARDIAC LEADS
Intended Purpose:	-

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 010275 0533 Rev. 09

Classification:	Class III
Device Group:	J010780 - ACTIVE IMPLANTABLE CARDIAC DEVICES REMOTE MONITORING SYSTEMS - HARDWARE ACCESSORIES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010201 - IMPLANTABLE DIAGNOSTIC ARRHYTHMIAS RECORDING CARDIAC DEVICES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010280 - CARDIAC DIAGNOSTIC DEVICES - ACCESSORIES
Intended Purpose:	-
Classification:	Class III
Device Group:	J019003 - ACTIVE-IMPLANTABLE CARDIAC SYSTEMS MAGNETISED DEVICES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010180 - IMPLANTABLE PACEMAKERS - ACCESSORIES
Intended Purpose:	-
Classification:	Class III
Device Group:	J010580 - IMPLANTABLE DEFIBRILLATORS - ACCESSORIES
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	none

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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable Class IIb Devices and Class III Devices)

No. G12 010275 0533 Rev. 09

Revision History:

Rev.	Dated	Report	Description
00	2019-09-17	713165832	-
01	2019-10-02	713165832	-
02	2021-03-08	713195077	-
03	2021-10-20	713216862	-
04	2022-02-08	713221748 / 713220923 / 713220916	-
05	2022-08-19	713228701	-
06	2022-08-31	713228701	-
07	2023-03-09	713267863	Supplemented: Device(s)/group of device(s) added
08	2023-04-21	713267858	Supplemented: Device(s)/group of device(s) added
09	2023-06-28	713277927	Supplemented: Device(s)/group of device(s) added

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Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 010275 0544 Rev. 00

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

SRN Manufacturer: DE-MF-000005049

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 010275 0544 Rev. 00

Report No.: 713229736

Valid from: 2023-02-09
Valid until: 2028-02-08

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-02-09

«LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHISINAU SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 010275 0544 Rev. 00

Classification:	III
Device Group:	J010501 - IMPLANTABLE SINGLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	4035479BUDI00053Q7
Intended Purpose:	Acticor, Rivacor are implantable cardioverter-defibrillators (ICDs: VR-T, VR-T DX and DR-T) and cardiac resynchronization therapy defibrillators (CRT-Ds: HF-T and HF-T QP). An ICD/CRT-D is part of an implantable system comprising an implantable ICD/CRT-D and leads. The primary function of the ICD system is the ability, first, to sense and record the intrinsic heart rhythm/rate and, second, to provide antitachycardia pacing by electrical pulses of low energy or a shock by electrical pulses of high energy, as well as to provide pacing by electrical pulses of low energy to ensure a stable heart rate or to support the intrinsic heart rate. CRT systems share all mentioned functions and in addition provide permanent sensing and pacing of the left ventricle. The implantation of an ICD/CRT-D is a symptomatic therapy with the following objectives: • Sensing and recording the heart rhythm and automatically detecting cardiac arrest (ICDs and CRT-Ds). • Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery(ICDs and CRT-Ds). • Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds). • Compensation of bradycardia through ventricular or AV sequential pacing (ICDs and CRT-Ds). • Cardiac resynchronization through multisite ventricular pacing (CRT-Ds, e.g., biventricular pacing).
Device(s):	Acticor 7 VR-T Rivacor 7 VR-T Rivacor 5 VR-T Rivacor 3 VR-T Acticor 7 VR-T DX Rivacor 7 VR-T DX Rivacor 5 VR-T DX

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EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 010275 0544 Rev. 00

Classification:	III
Device Group:	J010502 - IMPLANTABLE DUAL CHAMBER DEFIBRILLATORS
Basic UDI-DI:	4035479BUDI00053Q7
Intended Purpose:	Acticor, Rivacor are implantable cardioverter-defibrillators (ICDs: VR-T, VR-T DX and DR-T) and cardiac resynchronization therapy defibrillators (CRT-Ds: HF-T and HF-T QP). An ICD/CRT-D is part of an implantable system comprising an implantable ICD/CRT-D and leads. The primary function of the ICD system is the ability, first, to sense and record the intrinsic heart rhythm/rate and, second, to provide antitachycardia pacing by electrical pulses of low energy or a shock by electrical pulses of high energy, as well as to provide pacing by electrical pulses of low energy to ensure a stable heart rate or to support the intrinsic heart rate. CRT systems share all mentioned functions and in addition provide permanent sensing and pacing of the left ventricle. The implantation of an ICD/CRT-D is a symptomatic therapy with the following objectives: • Sensing and recording the heart rhythm and automatically detecting cardiac arrest (ICDs and CRT-Ds). • Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery(ICDs and CRT-Ds). • Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds). • Compensation of bradycardia through ventricular or AV sequential pacing (ICDs and CRT-Ds). • Cardiac resynchronization through multisite ventricular pacing (CRT-Ds, e.g., biventricular pacing).
Device(s):	Acticor 7 DR-T Rivacor 7 DR-T Rivacor 5 DR-T Rivacor 3 DR-T

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EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 010275 0544 Rev. 00

Classification:	III
Device Group:	J010503 - IMPLANTABLE TRIPLE CHAMBER DEFIBRILLATORS
Basic UDI-DI:	4035479BUDI00065QE
Intended Purpose:	Acticor, Rivacor are implantable cardioverter-defibrillators (ICDs: VR-T, VR-T DX and DR-T) and cardiac resynchronization therapy defibrillators (CRT-Ds: HF-T and HF-T QP). An ICD/CRT-D is part of an implantable system comprising an implantable ICD/CRT-D and leads. The primary function of the ICD system is the ability, first, to sense and record the intrinsic heart rhythm/rate and, second, to provide antitachycardia pacing by electrical pulses of low energy or a shock by electrical pulses of high energy, as well as to provide pacing by electrical pulses of low energy to ensure a stable heart rate or to support the intrinsic heart rate. CRT systems share all mentioned functions and in addition provide permanent sensing and pacing of the left ventricle. The implantation of an ICD/CRT-D is a symptomatic therapy with the following objectives: • Sensing and recording the heart rhythm and automatically detecting cardiac arrest (ICDs and CRT-Ds). • Termination of ventricular fibrillation (VF) or ventricular tachycardia (VT) through shock delivery(ICDs and CRT-Ds). • Termination of ventricular tachycardia (VT) through antitachycardia pacing (ATP) (ICDs and CRT-Ds). • Compensation of bradycardia through ventricular or AV sequential pacing (ICDs and CRT-Ds). • Cardiac resynchronization through multisite ventricular pacing (CRT-Ds, e.g., biventricular pacing).
Device(s):	Acticor 7 HF-T Rivacor 7 HF-T Rivacor 5 HF-T Rivacor 3 HF-T Acticor 7 HF-T QP Rivacor 7 HF-T QP Rivacor 5 HF-T QP Rivacor 3 HF-T QP
The validity of this certificate depends on conditions and/or is limited to the following:	none

«LIFE MED» S.R.L. IDNO 1014600035666 SUCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA, mun. CHIȘINĂU

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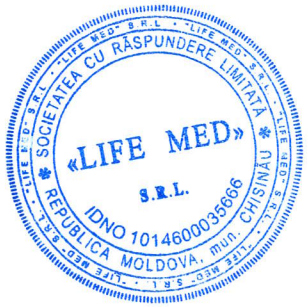
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

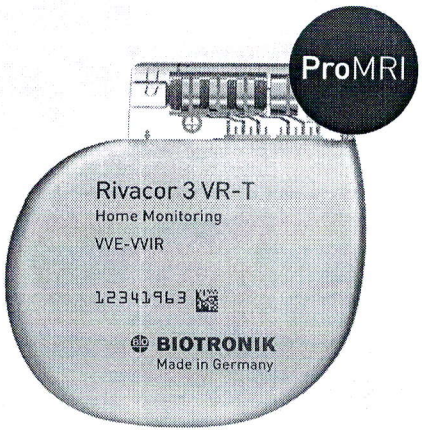
TÜV®

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
429574	Cardioverter-defibrilator monocameral	Rivacor 3 VR-T	Rivacor 3 VR-T		
429573	Cardioverter-defibrilator bicameral	Rivacor 3 DR-T	Rivacor 3 DR-T		



Rivacor 3 VR-T

MR conditional single-chamber ICD



Ordering Information

Model	Connectors	Volume/weight	Dimensions	Order number
Rivacor 3 VR-T	DF4 (LLHH) (1x)	30 cm^3/75 g	60 mm x 61.5 mm x 10 mm	429574

Product Highlights

BIOshape

BIOTRONIK Home Monitoring®

ProMRI[1)]

1) For combination of MR conditional devices, please see the "ProMRI MR conditional device systems" manual

ShockReduct

MorphMatch

Automatic threshold monitoring

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Rivacor 3 VR-T

Technical Data

Therapy and monitoring zones	
Bradycardia	30 ... (5) ... 100 ... (10) ... 160 bpm
VT1	OFF; 100; 102; 103 ... (2) ... 115; 118 ... (2) ... 122 ... (3) ... 128; 130 ... (3) ... 136; 140 ... (3) ... 146 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 bpm
VT2	OFF; 120; 122 ... (3) ... 128; 130 ... (3) ... 136; 140 ... (3) ... 146 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 bpm
VF	OFF; 150 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 ... (9) ... 240; 250 bpm
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval; Onset; Stability; MorphMatch; Sustained VT
Detection counter VT1	10 ... (2) ... 100
Detection counter VT2	10 ... (2) ... 80
Redetection counter VT1	10 ... (2) ... 50
Redetection counter VT2	10 ... (2) ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	OFF; 4 ... (4) ... 32 %
Stability	OFF; ± 8 ... (4) ... ± 48 ms and ± 8 ... (4) ... ± 48 %
MorphMatch	OFF; Monitoring; ON
MorphMatch threshold	Std.; Low; High
Sustained VT	OFF; 1 ... (1) ... 3; 5; 10 ... (10) ... 30 min
Tachycardia therapy (VT1/VT2 zone)	
Attempts	OFF; 1 ... (1) ... 10
ATP type	Burst; Ramp
Number S1	1 ... (1) ... 15
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %
ATP optimization	OFF; ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF ; Burst; Ramp
Stability criterion	12 % (fixed)
Number S1	1 ... (1) ... 15
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %
Cardioversions/defibrillation therapy	
Number of shocks	For VT zones: OFF; 1; 2; 6 or 8 For VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal; Reversed; Normal → alternating
Waveform (in VT1, VT2, VF)	Biphasic; Biphasic 2
Shock path (in VT1, VT2, VF)	RV → Can+SVC; RV → Can; RV → SVC
Energy of 1st shock	OFF; 2 ... (2) ... 20 ... (5) ... 40 J
Energy of 2nd shock	OFF; 4 ... (2) ... 20 ... (5) ... 40 J
Post-shock mode	VVI, if permanent: VVI(R), OFF
Post-shock pulse amplitude	7.5 V (RV)
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min

Pacing parameters	
Mode	VVIR; VVI; V00; OFF
Pulse amplitude (RV)	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V
Pulse width (RV)	0.4; 0.5 ... (0.25) ... 1.5 ms
Capture control (RV)	OFF; ATM
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm
Rate hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm
Scan/Repetitive	OFF; ON
Night rate	OFF; 30 ... (5) ... 100 bpm
Sensing (RV)	Std.; TWS; VFS
Sensor	Accelerometer
MRI program	ON; OFF; AUTO
Expiration date (for AUTO)	Adjustable to today's date + 14 days
Diagnostic functions	
Recording episodes For SVT	OFF; ON
Recording episodes For nsT	OFF; ON (<220ms); ON
Periodic recording (if Home Monitoring: OFF)	OFF; 30 ... (30) ... 120; 180 days
IEGM Holter	2 × 56 min (Far-field, RV)
Length of prehistory	Fixed: 30 s; 5 s (when onset was fulfilled or at induced episodes)
Physical parameters	
Telemetry	RF, programming head
Material	Titanium
Battery	3.2 V
Longevity	15.06 years[1] [1]RV: 2.5 V/0.4 ms, 40 bpm, 500 Ω; RV: 15 % pacing; 2 max. energy shocks/year; Home Monitoring: ON (daily transmission); diagnostics: ON
Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (EPE/ATP), conducRetrogradetion, Rapid ventricular pacing
Program sets	
Programs	Standard program; ProgramConsult; Individual program (1-3, individually programmable); First interrogated program; Safe program

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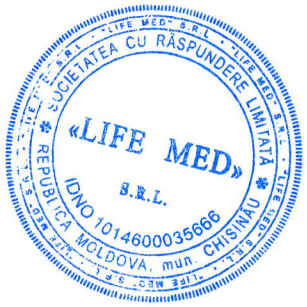
Transmitted data	Detection and therapy counters; Statistics; Lead measurement values; Battery and system status; ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF; ON
IEGM for therapy episodes	OFF; ON
IEGM for monitoring episodes	OFF; ON
Home Monitoring-supported follow-up	
Remote Scheduling	Enable; Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals varying from 20-366 days; Alignment with a specific day of the week; Only working days or no day alignment
Transmitted data	Periodic IEGM; Rate histogram (V); Device settings and statistics

Please refer to the technical manual of the device for further technical information.



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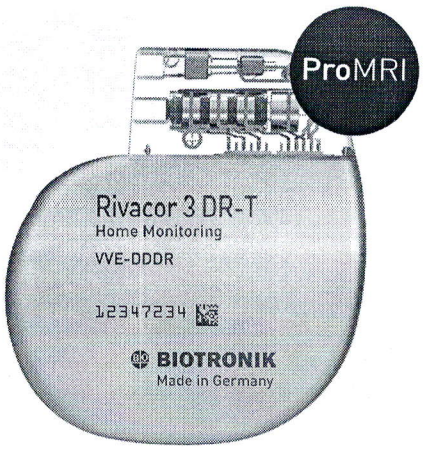
Rivacor 3 DR-T

MR conditional dual-chamber ICD



Ordering Information

Model	Connectors	Volume/weight	Dimensions	Order number
Rivacor 3 DR-T	DF4 (LLHH) (1x), IS-1 (1x)	32 cm³/77 g	60 mm x 66.5 mm x 10 mm	429573

Product Highlights

BIOshape

BIOTRONIK Home Monitoring®

Heart Failure Monitor

ProMRI[1)]

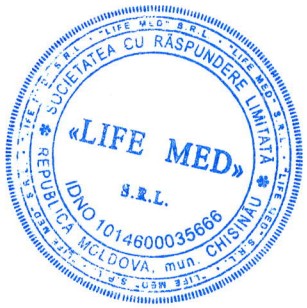
1) For combination of MR conditional devices, please see the "ProMRI MR conditional device systems" manual

ShockReduct

SMART

MorphMatch

Automatic threshold monitoring (RA, RV)



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Rivacor 3 DR-T

Technical Data

Therapy and monitoring zones	
Bradycardia	30 ... (5) ... 100 ... (10) ... 160 bpm
AT/AF	100 ... (10) ... 250 bpm
VT1	OFF; 100; 102; 103 ... (2) ... 115; 118 ... (2) ... 122 ... (3) ... 128; 130 ... (3) ... 136; 140 ... (3) ... 146 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 bpm
VT2	OFF; 120; 122 ... (3) ... 128; 130 ... (3) ... 136; 140 ... (3) ... 146 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 bpm
VF	OFF; 150 ... (4) ... 162; 167; 171; 176 ... (6) ... 200 ... (7) ... 214; 222 ... (9) ... 240; 250 bpm
Ventricular arrhythmia detection and redetection	
VT detection criteria	Interval; SMART detection; Onset; Stability; MorphMatch (if SMART: OFF); Sustained VT
Detection counter VT1	10 ... (2) ... 100
Detection counter VT2	10 ... (2) ... 80
Redetection counter VT1	10 ... (2) ... 50
Redetection counter VT2	10 ... (2) ... 40
Detection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30; 30 out of 40
Redetection counter VF	6 out of 8; 8 out of 12; 10 out of 14; 12 out of 16; 16 out of 20; 18 out of 24; 20 out of 26; 22 out of 30; 24 out of 30
Onset	If SMART = OFF: OFF; 4 ... (4) ... 32 % If SMART = ON: 4 ... (4) ... 32 %
Stability	If SMART = OFF: OFF; ± 8 ... (4) ... ± 48 ms and ± 8 ... (4) ... ± 48 % If SMART = ON: ± 8... (4) ... ± 48 %
MorphMatch	OFF; Monitoring; ON
MorphMatch threshold	Std.; Low; High
Sustained VT	OFF; 1 ... (1) ... 3; 5; 10 ... (10) ... 30 min
SMART detection	OFF; ON
Tachycardia therapy (VT1/VT2 zone)	
Attempts	OFF; 1 ... (1) ... 10
ATP type	Burst; Ramp
Number S1	1 ... (1) ... 15
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %
ATP optimization	OFF; ON
Minimum ATP interval	200 ms (fixed)
Tachycardia therapy (VF zone)	
ATP type (ATP One Shot)	OFF ; Burst; Ramp
Stability criterion	12 % (fixed)
Number S1	1 ... (1) ... 15
R-S1 interval	70 ... (5) ... 85; 88; 90; 95 %
Cardioversions/defibrillation therapy	
Number of shocks	For VT zones: OFF; 1; 2; 6 or 8 For VF zone: 6 or 8
Confirmation (in VT1, VT2, VF)	OFF; ON
Polarity (in VT1, VT2, VF)	Normal; Reversed; Normal → alternating
Waveform (in VT1, VT2, VF)	Biphasic; Biphasic 2
Shock path (in VT1, VT2, VF)	RV → Can+SVC; RV → Can; RV → SVC
Energy of 1st shock	OFF; 2 ... (2) ... 20 ... (5) ... 40 J
Energy of 2nd shock	OFF; 4 ... (2) ... 20 ... (5) ... 40 J
Post-shock mode	VVI; DDI; VDI
Post-shock pulse amplitude	7.5 V (RV, RA)
Post-shock duration	OFF; 10 s; 30 s; 1 min; 2 min; 5 min; 10 min
Pacing parameters	
Mode	DDDR; DDIR; VVIR; AAIR; D00; DDD; DDI; VVI; AAI; V00; VDDR; VDIR; VDD; VDI; OFF
Pulse amplitude (A, RV)	0.5 ... (0.25) ... 4.0 ... (0.5) ... 6.0; 7.5 V
Pulse width (A, RV)	0.4; 0.5 ... (0.25) ... 1.5 ms
Capture control (A, RV)	OFF; ATM
Basic rate	30 ... (5) ... 100 ... (10) ... 160 bpm
Rate hysteresis	OFF; -5 ... (-5) ... -25 ... (-20) ... -65 bpm
Scan/Repetitive	OFF; ON
Night rate	OFF; 30 ... (5) ... 100 bpm

Pacing parameters	
AV dynamics	Low; Medium; High; Fixed
AV delay after pacing and sensing	15; 40 ... (5) ... 350 ms
Sense compensation	OFF; -5 ... (-5) ... -120 ms
AV hysteresis mode	OFF; Positive; Negative; IRSplus
AV hysteresis mode (IRSplus)	400 ms (fixed)
AV scan/repetitive (Positive)	OFF; ON
Upper rate	90 ... (10) ... 170 bpm
Atrial upper rate	OFF; 175; 200; 240 bpm
Mode switching (Mode)	VDI, VDIR; DDI, DDIR
Intervention rate	OFF; 120 ... (10) ... 200 bpm
Change of basic rate during MS	OFF; +5 ... (5) ... +30 bpm
Post mode switching rate	OFF; +5 ... (5) ... +50 bpm
Post mode switching duration	1 ... (1) ... 30 min
Onset criterion/ Resolution criterion	3 ... (1) ... 8 out of 8
PVARP	AUTO; 175 ... (25) ... 600 ms
PMT detection/termination	OFF; ON
Sensing (RV)	Std.; TWS; VFS
Sensing (A)	Std.; OFF
Sensor	Accelerometer
MRI program	ON; OFF; AUTO
Expiration date (for AUTO)	Adjustable to today's date + 14 days
Diagnostic functions	
Recording episodes For AT/AF	OFF; ON
Recording episodes For SVT	OFF; ON
Recording episodes For nsT	OFF; ON (<220ms); ON
Periodic recording (if Home Monitoring: OFF)	OFF; 30 ... (30) ... 120; 180 days
IEGM Holter	3 × 56 min (Far-field, A and RV)
Length of prehistory	Fixed: 30 s; 5 s (when onset fulfilled or at induced episodes); 1 min for AT/AF episode if Advanced ON was programmed
Physical parameters	
Telemetry	RF, programming head
Material	Titanium
Battery	3.2 V
Longevity	12.52 years[1] [1]RA, RV: 2.5 V/0.4 ms, 60 bpm, 500 Ω; RV: 15 %, RA: 50 % pacing; 2 max. energy shocks/year; Home Monitoring: ON (daily transmission); diagnostics: ON
Tests	
Different tests for	Impedance, Sensing, Pacing threshold, DFT (EPE/ATP), Retrograde conduction, Rapid ventricular pacing
Program sets	
Programs	Standard program; ProgramConsult; Individual program (1-3, individually programmable); First interrogated program; Safe program

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Transmitted data	AF diagnostics; Heart Failure Monitor diagnostics; Detection and therapy counters; Statistics; Lead measurement values; Battery and system status; ICD program parameters
Message types	
Trend message	Triggered automatically once every 24 hours
Event message	Triggered automatically after certain cardiac events
Test message	Triggered manually via programmer
Programmer settings	
Home Monitoring	OFF; ON
IEGM for therapy episodes	OFF; ON
IEGM for monitoring episodes	OFF; ON
Ongoing atrial episode	OFF; 6 h; 12 h; 18 h
Home Monitoring-supported follow-up	
Remote Scheduling	Enable; Disable
HM follow-up intervals/alignment	Individually programmable first date and repetition intervals varying from 20-366 days; Alignment with a specific day of the week; Only working days or no day alignment
Transmitted data	Periodic IEGM; Rate histogram (V); Device settings and statistics

Please refer to the technical manual of the device for further technical information.

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