Anexă nr 1

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 83 din 21 septembrie 2023

Solicitantul **„Life Med”** SRL , cu sediul *mun. Chișinău, Republica Moldova str. Tudor Strișcă, 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 și punerea la dispoziție pe piață a:

1) Cateter pentru electrofiziologie diagnostic ViaCatch ;

Se anexează următoarele acte:
DC 21 03 0123 M0074 in numar de 2 pagini, EC G7 019742 0093 Rev. 01 in numar de 2 pagini, EC G1 019742 0092 Rev.01 în număr de 2 pagini

Data 21.09.2023 Semnătura

Tabelul de recepționare a notificării

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

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

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) Cateter pentru electrofiziologie diagnostic ViaCatch

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia *Semnătura* _____

Administrator Railean Efimia *Data* 21.09.2023

VascoMed

VascoMed GmbH • Hertzallee 1 • D-79589 Binzen, Germany

To Whom It May Concern

VascoMed GmbH
Tel +49(0)7621 16011-0
Fax +49(0)7621 16011-9191
E-mail info@vascomed.com
www.vascomed.com

Binzen, 14. December 2022

Tender №1663342194003

Letter of Authorization

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

Products concerned:
AlCath
MultiCath

We, VascoMed GmbH, Hertzallee 1, 79589 Binzen, Germany, hereby permit our distributor BIOTRONIK SE & Co. KG, Woermannkehre 1, 12359 Berlin, Germany, represented in Moldova "LIFE MED" S.R.L., str. Doctor Tudor Strișcă, 30, mun. Chișinău, Republica Moldova, in relation to the tender №1663342194003, to non-exclusively 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 (ablation and diagnostic catheters) 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 December 31, 2023.

VascoMed GmbH

VascoMed GmbH
Hertzallee 1 • D-79589 Binzen • Germany
Tel +49(0)7621-16011-0 • Fax +49(0)7621-16011-9191

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

Katja Majoros
Vice President – QM and Regulatory Affairs

Geschäftsführer: Dr. Wolfgang Geistert
Amtsgericht Freiburg HRB 411576
VAT Nr.: DE142398878

Postbank Berlin
IBAN: DE18 1001 0010 0092 1121 07
BIC: PBNKDEFF100

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 019742 0092 Rev. 01

Manufacturer:

VascoMed GmbH
Hertzallee 1
79589 Binzen
GERMANY

Product Category(ies):

**Ablation Catheters,
Temporary Catheters and Electrodes for Stimulation and Electrophysiology Diagnostics,
Accessories for Catheters and Electrodes**

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. 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:G1 019742 0092 Rev. 01

Report No.: 713203432

Valid from: 2021-03-01
Valid until: 2024-05-26

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

Date, 2021-03-01

Christoph Dicks
Head of Certification/Notified Body

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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www.zlg.de
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 019742 0092 Rev. 01

Design Facility(ies): VascoMed GmbH
Hertzallee 1, 79589 Binzen, GERMANY

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

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 019742 0093 Rev. 01

Manufacturer: **VascoMed GmbH**
Hertzallee 1
79589 Binzen
GERMANY

Product: **Cardiac Diagnostic Catheters**

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 MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. 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:G7 019742 0093 Rev. 01

Report no.: 713201688

Valid from: 2021-02-23
Valid until: 2024-05-26

Date, 2021-02-23

Christoph Dicks
Head of Certification/Notified Body

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

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www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

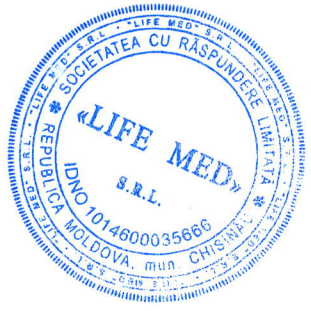
No. G7 019742 0093 Rev. 01

Model(s): **ViaCath, AcQRate Dx Steerable Catheter**

Parameter:

Product group	Model name	Model number
ViaCath NG	ViaCath NG 4/S/5mm	351197
	ViaCath NG 4/S/10mm	351196
	ViaCath NG 10/S/2-6-2mm	351200
	ViaCath NG 10/L/2-6-2mm	358797
	ViaCath NG 10/L/2-8-2mm	370309
	ViaCath NG 10/XL/2-10-2mm	370144
ViaCath	ViaCath 20/XL/2-10-2mm	351201
AcQRate Dx Steerable Catheter	AcQRate Dx Steerable Catheter 4/S/5mm	460656
	AcQRate Dx Steerable Catheter 4/S/10mm	460657
	AcQRate Dx Steerable Catheter 10/S/2-6-2mm	460658
	AcQRate Dx Steerable Catheter 10/L/2-6-2mm	460659
	AcQRate Dx Steerable Catheter 10/L/2-8-2mm	460660
	AcQRate Dx Steerable Catheter 10/XL/2-10-2mm	460661
	AcQRate Dx Steerable Catheter 20/XL/2-8-2mm	460662

Explanation of the abbreviations:
ViaCath (NG) n / c / s
n Number of electrodes
c Curve design (S = Standard, L = Large, XL = Extra Large)
s Electrode spacing (in mm)



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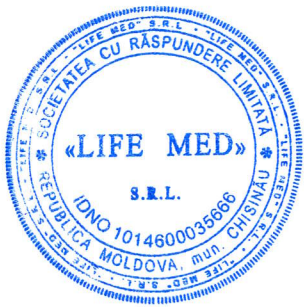
Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Tip dispozitiv	Cod GMDN
351 200	Catetere orientabile pentru diagnosticul electrofiziologic	ViaCath NG 10/S/2-6-2 mm Standard			
358 797	Catetere orientabile pentru diagnosticul electrofiziologic	ViaCath NG 10/L/2-6-2 mm			
370 309	Catetere orientabile pentru diagnosticul electrofiziologic	ViaCath NG 10/L/2-8-2 mm Large			
370 144	Catetere orientabile pentru diagnosticul electrofiziologic	ViaCath NG 10/XL/2-10-2 mm Extra Large			
351 201	Catetere orientabile pentru diagnosticul electrofiziologic	ViaCath 20/XL/2-8-2 mm			



ViaCath 10-Pole

Steerable Diagnostic Catheter

Ordering Information

Model	Curve	Spacing	Shaft Diameter	Length	Order Number
ViaCath NG 10/S/2-6-2 mm	Standard	2-6-2 mm	6 F	110 cm	351200
ViaCath NG 10/L/2-6-2 mm	Large	2-6-2 mm	6 F	110 cm	358797
ViaCath NG 10/L/2-8-2 mm	Large	2-8-2 mm	6 F	110 cm	370309
ViaCath NG 10/XL/2-10-2 mm	Extra Large	2-10-2 mm	6 F	110 cm	370144

Product Highlights

Handling
Rotational symmetric handle platform with push-pull steering

Wide product range
Multiple curve sizes for use in various anatomies

Connection
Only two BIOTRONIK cables (MPK-4-R or MPK-10-R) are necessary to connect all ViaCath and MultiCath catheters

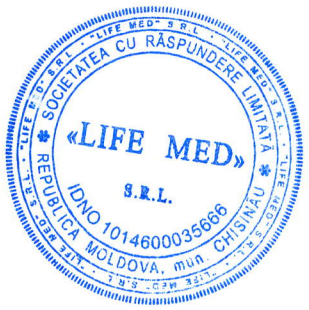
BIOTRONIK
excellence for life

ViaCath 10-Pole

Technical Data

Catheter Specification	
Tip electrode length	2 mm
Tip electrode type	Standard
Ring electrode length	1 mm
Number of electrodes	10
Electrode spacing	2-6-2, 2-8-2, 2-10-2 mm
Electrode material	Platinum Iridium (Pt/Ir)
Shaft diameter	6 F (2.0 mm)
Curve type	Standard, Large, Extra Large
Curve shape	Steerable
Effective catheter length	110 cm
Connection plug	10-pole connector (REDEL), female, 0°coded
Patient cable	MPK-10-R

Transport and Storage Conditions	
Storage	Please store this sterile product in the original sterile packaging
Light	Keep away from sunlight



Status 06/2021

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