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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 541900**

Issued To: **Merit Medical Systems, Inc.**
1600 West Merit Parkway
South Jordan
Utah
84095
USA

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

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

First Issued: **2008-10-03** Date: **2018-10-01** Expiry Date: **2023-10-02**

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Certificate No: CE 541900

Certificate Scope:

The design, development and manufacture of sterile angiographic, angioplasty and other procedure kits/packs, angiographic catheters, cardiac catheters, vascular catheters, peripheral catheters, guiding catheters, guide wires (coated and uncoated), vascular trocars, introducer needles, angiographic needles, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, snare devices, hemostasis devices, balloon inflation systems, scalpels, tubing, manifolds/stopcocks, valves, syringes, tracheobronchial stent systems, esophageal stent systems, biliary stent systems, stent positioning system intended for coronary or renal interventional procedures, Peritoneal Dialysis Catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts, graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications, percutaneous transluminal angioplasty (PTA) catheters, caps for the disinfection of vascular access connectors.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of angiographic, angioplasty and other procedure kits/packs, anesthesia conduction catheter fixation devices, catheter flush devices, infusion systems, syringes, suture retention devices, torque devices, drainage/waste/sharps collection devices, surgical/general purpose organizers, abdominal binders, labeling sets, compression devices, balloon inflation systems, non-vascular balloon catheter systems and all related accessories.

Those aspects of Annex II related to metrology in the manufacture of syringes, pressure monitors, tracheal measuring devices, balloon inflation systems and all related accessories.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035665 REPUBLICA MOLDOVA, mun. CHIȘINĂU

First Issued: **2008-10-03** Date: **2018-10-01** Expiry Date: **2023-10-02**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Abbott Vascular
3200 Lakeside Drive
Santa Clara
California
95054
USA

Holds Certificate No: **FM 72377**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

Design and Development, Manufacture and Distribution of: Everolimus-eluting coronary scaffolding/stent and delivery systems (absorbable, non-absorbable); coronary and peripheral stent and delivery systems; coronary covered stent systems; coronary and peripheral dilatation catheters; carotid stent and delivery systems; embolic protection systems; arterial vessel closure devices and the related deployment instruments; mitral valve repair systems including clip and delivery systems, steerable guide catheters and stabilizer accessories; guide wires and related cardiovascular accessories.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 12/27/2002 Effective Date: 09/22/2016 Expiry Date: 02/28/2019

CMDCAS Recognized Registrar

SCC Accredited CB-MS OCSM Accrédité CCN

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«LIFE MED» S.R.L. IDNO 1014600035065 REPUBLICA MOLDOVA

Certificate No: FM 72377

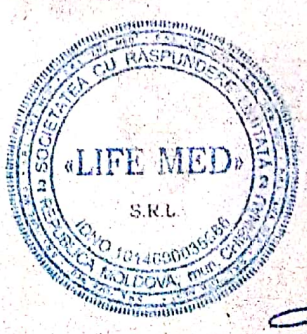
Location	Registered Activities
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	Design and development, manufacture and distribution of Everolimus eluting coronary scaffolding systems (including delivery systems). Manufacture and distribution of coronary and peripheral stents and delivery system, including covered stents, dilatation catheters, arterial vessel closure devices and the related instruments necessary for the deployment of the closure devices, guide wires, and accessories.
Abbott Vascular 3200 Lakeside Drive Santa Clara California 95054 USA	Design, development, manufacture and distribution of coronary and peripheral stents and delivery system, including covered stents, dilatation catheters, arterial vessel closure devices and the related instruments necessary for the deployment of the closure devices, guide wires, and accessories. In addition, sterilization by Electron Beam Processor for medical devices. Design, manufacture, final inspection and distribution of sterile cardiac and vascular stent systems. Design and Development, Manufacture (including radiation sterilization) and Distribution of Everolimus-eluting coronary scaffolding systems and Design and Development, Manufacture and distribution of Everolimus-eluting coronary and peripheral stenting systems.
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	Manufacture of stent delivery catheters and systems, dilatation catheters and guide wires, sterilization by Electron Beam Processor for medical devices. Development of cardiovascular accessories. Design, development and manufacture (including radiation sterilization) of Everolimus-eluting coronary scaffolding systems.
Abbott Vascular 3885 Bohannan Drive Menlo Park California 94025 USA	Design, development and manufacture of sterile mitral valve repair systems and associated accessories.
Abbott Vascular 52 Calle 3, B31 Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	Manufacture of dilatation catheters.

«LIFE MED» S.R.L.

Original Registration Date: 12/27/2002 Effective Date: 09/22/2016 Expiry Date: 02/28/2019

Certificate No: **FM 72377**

Location	Registered Activities
Abbott Vascular Storage and distribution center 42301 Zevo Drive Temecula California 92590 USA	Storage and distribution center. Packaging of drug eluting stent systems and the Absorb bioresorbable vascular scaffold system. Secondary labeling for international markets.



Original Registration Date: 12/27/2002 Effective Date: 09/22/2016 Expiry Date: 02/28/2019

BAYTEKS®
TEKNİK TEKSTİL SAN. ve TİC. A.Ş.

March 25, 2019

AUTHORIZATION LETTER

To Whom it may Concern,

We as

BAYTEKS TEKNİK TESKTİL SANAYI VE TİCARET A.Ş.

with office at

Başpınar O.S.B. Mh. O.S.B. 5. Böl. 83514 Nolu Cad. No. 18
Şehitkamil/Gaziantep Turkey

hereby solemnly declares and confirms that

LIFE MED SRL
with Office at
C/f 1014600035666 Republica Moldova, or. Chişinău, str. Tudor Strișcă, 30

is entitled non exclusively to offer for sale in The Republic of Moldova the products of the brand BAYMED manufactured by BAYTEKS TEKNİK TEKSTİL SANAYI VE TİCARET A.Ş. commercialized and distributed by BAYDIS TİCARET A.Ş.

The letter is only issued tender participation in the Republic of Moldova.

This letter is valid within the year 2019 starting from this date until December 2019. The present letter can be terminated any time with a one-month's written notice period.

LIFE MED SRL have been awarded during this period the right of substition to meet and perform all obligations arisen in terms of the Tender

Authorized Signatory by BAYTEKS TEKNİK TEKSTİL SANAYI VE TICARET A.Ş.

This authorization letter is dated on the 25 March 2019.

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

BAYTEKS
TEKNİK TEKSTİL SAN. ve TİC. A.Ş.
Mük: Başpınar O.S.B. Mh. O.S.B. 5.Böl. 83514 Nolu Cad. No.18
Şehitkamil/GAZİANTEP Mersis No.: 0159 0038 749 0017
Tel:0348 822 1060 (Pbx) Fax:0348 834 1028, Tic.Sic.No.3976
ŞEHİTKAMİL V.D.: 159 003 8749 www.bayteks.com

CERTIFICATE

kiwa

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-18-479

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ

Organize Sanayi Bölgesi 19 nolu Cad. No:9 Merkez /Kilis-Turkey

Products: Sterile Disposable Surgical Gown, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:	M.5035.02
Date of first issue:	12 January 2018
Date of last issue:	01 March 2019
Revision Number:	02
Expiry Date:	11 January 2021

Kiwa Certification Services Inc. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

01 March 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
ITOSB 9. Cad. No:16 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

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

CERTIFICATE

No. Q5 17 06 63599 033

Holder of Certificate: **Beijing Domax Medical Technology Co.,Ltd**
A13-7, Jingshengnansi Street, Tongzhou District
101102 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Beijing Domax Medical Technology Co.,Ltd
A13-7, Jingshengnansi Street, Tongzhou District,
101102 Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Sales of Manifolds, Y connector pack, control syringes, pressure line, Balloon In-deflation Device, Push-Click Y Connector Kit, Interventional Device Set; PTCA Balloon Dilatation Catheter, Disposable Pressure Transducer, Interventional Procedure Pack.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1792002

Valid from: 2017-11-14
Valid until: 2019-10-31

Date, 2017-11-14

Stefan Preiß

«LIFE MED» S.R.L. IDNO 1014600035665 SOCIETATEA CU RĂS... REPUBLICA MOLDOVA, mun. CHIȘINĂU

DAkkS

Page 1 of 1

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 06 63599 031

Manufacturer:

Beijing Demax Medical Technology Co.,Ltd
A13-7, Jingshengnansi Street, Tongzhou District
101102 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Manifolds, Y Connector Pack, Control Syringes, Pressure Line, Push-Click Y Connector Kit, Interventional Device Set, Disposable Pressure Transducer.

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.: BJ17920071

Valid from: 2017-11-08
Valid until: 2022-11-07

Date, 2017-10-23

Stefan Preiß

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 17 06 63599 031

Facility(ies):

Beijing Demax Medical Technology Co.,Ltd.
A13-7, Jingshengnansi Street, Tongzhou District, 101102 Beijing,
PEOPLE'S REPUBLIC OF CHINA

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035686 REPUBLICA MOLDOVA, mun. CHIȘINĂU

TÜV®

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By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00340**

Issued To: **Cordis Corporation**
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

«LIFE MED» S.R.L.

In respect of:

The design, development and manufacture of sterile intravascular diagnostic and interventional catheters, biopsy forceps, needles, catheter extensions, coronary and peripheral guidewires, embolic capture guidewire systems, introducer guides, metallic vascular and biliary stents and delivery systems and vascular closure devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **30 November 1994** Date: **13 December 2015** Expiry Date: **25 November 2019**

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MEDICAL CONMED EQUIPMENT
Calea Mosilor nr. 158, etaj 2, biroul 2A
20883 Bucuresti
email: office@medconmed.ro tel mob: +4 0722.216.916
web: www.medconmed.ro fax: +4 031 427 0725

Catre: 021901 / 25.03.2019

Attn:

SCRISOARE DE AUTORIZARE

Prin prezenta, SC Medical ConMed Equipment srl, cu sediul in Bucuresti, Calea Mosilor 158, sect. 2, VAT RO25291509, J40/3493/2009, ca distribuitor CE a companiilor Cordis, Demax, autorizam prin prezenta firma sa distribuie materialele sanitare furnizate de la firmele mentionate mai sus.

Multumesc,

Tudor Ionici

MEDICAL CONMED EQUIPMENT S.R.L.

«LIFE MED» S.R.L.