EC CERTIFICATE

Number: 3812454CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

For the product category(ies)

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August, 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 14 December 2023
Issued for the first time: 1 July 2014

Revised: 21 December 2018
Reissued: 14 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 510108**

Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

The design, development and manufacture of coronary and peripheral dilation catheters, stent systems, including covered stents, drug eluting stents, Bioresorbable Vascular Scaffold (BVS) Systems, carotid and peripheral stent systems, embolic protection systems, arterial vessel closure devices and the related instruments necessary for the deployment of the closure devices, guidewires, mitral valve repair systems, and associated accessories.

Those aspects of Annex II related to securing and maintaining the sterility of guide wire extensions, torque devices, hemostatic valves, introducers and flushing tools.

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: **01 August 2006** Date: **13 July 2016** Expiry Date: **16 October 2020**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

bsi.

By Royal Charter

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

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

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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

bsi.

By Royal Charter

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.

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

...making excellence a habit.

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Design-Examination Certificate
No. 10 0969 CN/NB

issued for manufacturer

Meril Life Sciences Pvt. Ltd.

Muktanand Marg, Chala, Vapi - 396191, Gujarat, India

in accordance with requirements of

Directive 93/42/EEC

on medical devices, Annex II (4)

for the following product category(ies):

Drug-eluting coronary artery stent, bioabsorbable-polymer-coated

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2017-11-14
Valid until: 2022-11-13
First Issued: 2010-11-30
Revision: f

NOTIFIED BODY 1023

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

Date: 2017-11-14

RNDr. Radomir Čevelík
Representative of the Notified Body No. 1023

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

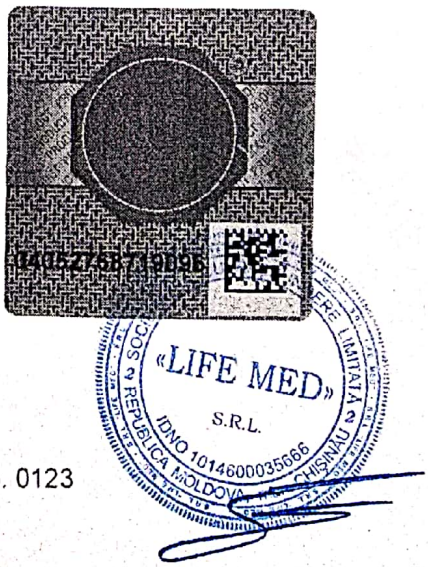
Product Category(ies):

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

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 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

TÜV®

bsi.

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

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**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60118775 0001

Report No.: 17054840 003

Manufacturer:
Shunmei Medical
Co., Ltd.
R401 of building B, No.8 of
1st Jinglong Road, Baolong
Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60107860 0001

Expiry Date: 2021-03-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body: TÜV Rheinland LGA Products GmbH, TÜVRheinland, Zertifizierungsstelle, X. Ren

Effective Date: 2017-08-29

Date: 2017-08-29

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197

«LIFE MED» S.R.L. IDNO 1014600035566 REPUBLICA MOLDOVA, mun. CHISINAU SOCIETATEA CU RASPUNDERE LIMITATA

EC CERTIFICATE

Number: 2107788CE12

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

ASAHI INTECC CO., LTD. Medical Division
3-100 Akatsuki-cho, Seto,
Aichi 489-0071
JAPAN

For the product category(ies)

Guide Wires for PTCA and PTA

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2107788CN
Addendum, initially dated 15 March 2010

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 15 March 2019
Issued for the first time: 15 March 2010
Reissued: 4 February 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V, Article 3

Quality Assurance System Production

Medical Devices

Registration No.: OD 69246606 0001
Replaces approval: OD 69240939 0001

Report No.: 28211468 004

Manufacturer: 3 Teks Tekstil Gida Ithalat Ihracat San.Tic.LTD.STI
2.Organize Sanayi Bölgesi, No:1, Baspinar,
27650 Gaziantep – TURKEY

Products:

GMDN code	REF, Name
17881	EVLA SET
17881	PLDD SET
17881	EVA SET

(See attachment for complete product list)

The Notified Body audited the quality system and certifies that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned directive.

Issue Date: 2014-05-09

Effective Date: 2014-05-09

Expiry Date: 2019-05-08

Notified Body

TÜV Rheinland InterCert Kft. TÜVRheinland 5 Notified Body 1008

Zoltán Ambrus MD.

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

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

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

TÜVRheinland®

ATTACHMENT

Registration No.: OD 69246606 0001
Replaces approval: OD 69240939 0001

Report No.: 28211468 004

Manufacturer: 3 Teks Tekstil Gida Ithalat Ihracat San.Tic.LTD.STI 2.Organize Sanayi Bölgesi, No:1, Baspinar,

27650 Gaziantep – TURKEY

Products:

GMDN code	REF, Name
35833	İnfusion Set Standart
36530	Peristaltic Pump Infusion Sets
17569	Sclerotherapy Liquid Infussion Sets
44545	Y- Connector
32172	Stopcoks
32172	Manifolds
32337	Puncture/ Introducer Needles
36177	Insertion Tools
15286	Control Syringes
12170	Pressure Line
12170	Extension Line
16545	Manifold Kit
10678	Percutaneous Introducer Set (Introducer Sheath)
44545	Y-Connector Kit
11969	Tubing Sets
16163	Cardioplegia Perfusion Sets
31296	Tubes

TÜV Rheinland InterCert Kft. TÜVRheinland® 5. Notified Body 1008

Notified Body

Zoltán Ambrus MD.

Budapest, 2014-05-09

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

«LIFE MED... S.R.L.

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

TÜVRheinland®

ATTACHMENT

Registration No.: OD 69246606 0001
Replaces approval: OD 69240939 0001

Report No.: 28211468 004

Manufacturer: 3 Teks Tekstil Gida Ithalat Ihracat San.Tic.LTD.STI 2.Organize Sanayi Bölgesi, No:1, Baspinar,

27650 Gaziantep – TURKEY

Products:

GMDN code	REF, Name
38568	Connectors
38568	Connectors
17580	Arterial Filter
15649	Oxygen Filter
17580	Pre-bypass Filter
17501	Spikes (Vented, Non-vented)
17501	Drip Chamber
34894	Yankauer Cannula
18018	Check Valve
13803	Stopcock

TÜV Rheinland InterCert Kft. TÜVRheinland® 5 Notified Body 1008

Notified Body

Budapest, 2014-05-09

Zoltán Ambrus MD.

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

«LIFE MED» S.R.L.

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.

TÜVRheinland®

ATTACHMENT

Registration No.: OD 69246606 0001
Replaces approval: OD 69240939 0001

Report No.: 28211468 004

Manufacturer: 3 Teks Tekstil Gida Ithalat Ihracat San.Tic.LTD.STI 2.Organize Sanayi Bölgesi, No:1, Baspinar,

27650 Gaziantep – TURKEY

Aspects of manufacture concerned with securing and maintaining sterile conditions applies to the following products:

Products:

GMDN code	REF, Name
17807	Optical Fiber
34099	Vein Valves and Sets
36177	Torquer
17541	Inflation Device
15646	Disposable Surgical Drapes
11901	Disposable Surgical Gowns

TÜV Rheinland InterCert Kft. TÜVRheinland 5 Notified Body 1008

Notified Body

Zoltán Ambrus MD.

Budapest, 2014-05-09

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/

«LIFE MED» S.R.L.

TÜV Rheinland InterCert Kft. is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 1008.