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 RASPUNDERE LIMITATA «LIFE MED» S.R.L. IDNO 1014600036686 REPUBLICA MOLDOVA, mun. CHIŞINĂU

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

ADDENDUM

Belonging to certificate: 3812454CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

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.

Issued to:

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

This certificate covers the following location(s):

Location Code	Company name / address	Location Code	Company name / address
MAR2	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA	CR2	Boston Scientific Corporation 2546 First Street, Propark El Coyol Alajuela Costa Rica
COR	Boston Scientific Limited Business & Technology Park Model Farm Rd Cork, Ireland	GAL	Boston Scientific Limited Ballybrit Business Park Galway, Ireland
COV	Boston Scientific Corporation 8 Industrial Drive Coventry, RI 02816 USA	KER	Boston Scientific International BV European Centre of Operations Vestastraat 6, 6468 EX Kerkrade, The Netherlands

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

«LIFE MED» S.R.L.

ADDENDUM

Belonging to certificate: 3812454CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

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.

Issued to:

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

This certificate covers the following location(s):

Location Code	Company name / address	Location Code	Company name / address
CR1	Boston Scientific Corporation 302 Parkway Global Park, Heredia Costa Rica	MAR	Boston Scientific Corporation 100 Boston Scientific Way Marlborough, MA 01752 USA
MG2	Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA	SJ2	Boston Scientific Corporation 150 Baytech Drive San Jose, CA 95134 USA
PL2	Boston Scientific Corporation 5905 Nathan Lane Plymouth, MN 55442 USA	SPE	Boston Scientific Corporation 780 Brookside Drive Spencer, IN 47460 USA

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

«LIFE MED» S.R.L.

ADDENDUM

Belonging to certificate: 3812454CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

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.

Issued to:

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

This certificate covers the following location(s):

Location Code	Company name / address
QUI	Boston Scientific Corporation Marina Bay Customer Fulfillment Center 500 Commander Shea Blvd Quincy, MA 02171 USA

Initial date: 1 July 2014
Revision date: 21 December 2018

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

sc Medical Devices & Diagnostics s.r.l.
Adresa: Drumul Valea Furcii nr 111C, sector 6, Bucuresti
Tel/fax: +4021 3148044; email: office@mdd.ro ; web: www.mdd.ro
CUI: RO25045148; Reg Com. J40/1487/2009; Cont: RO36BACX0000000331286000 Unicredit Bank

NR. MDD76/25.03.2019

SCRISOARE DE AUTORIZARE

Catre:

Republica Moldova, Mun.Chişinău, str.Tudor Strisca 30

Noi, **MEDICAL DEVICES & DIAGNOSTICS s.r.l.**, cu sediul social in Bucuresti, Drumul Valea Furcii, Nr.111C, Sector 6, J40/1247/2009, CUI RO25045148, **in calitate de unic importator in Romania si Republica Moldova** al producatorilor Abbott Vascular si Merit Medical, **desemnăm prin prezenta societatea:**

SC LIFE MED SRL
IDNO: 1014600035666
VAT: 0208964
Address: **str.Tudor Strisca 30 Chisinau, Moldova**

Ca reprezentant autorizat pe teritoriul Republicii Moldova, din numele producătorului Abbott Vascular.

Cu stima,
Director General
Udrescu Liviu Gheorghe

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

sc Medical Devices & Diagnostics s.r.l.
Adresa: Drumul Valea Furcii nr 111C, sector 6, Bucuresti
Tel/fax: +4021 3148044; email: office@mdd.ro ; web: www.mdd.ro
CUI: RO25045148; Reg Com. J40/1487/2009; Cont: RO36BACX0000000331286000 Unicredit Bank

NR. MDD 77/25.03.2019

SCRISOARE DE AUTORIZARE

Catre:

Republica MoldovStr.Tudor Strisca 30, Chisinau, MD-2043a, Mun.Chişinău,

Noi, **MEDICAL DEVICES & DIAGNOSTICS s.r.l.**, cu sediul social in Bucuresti, Drumul Valea Furcii, Nr.111C, Sector 6, J40/1247/2009, CUI RO25045148, **in calitate de unic importator in Romania si Republica Moldova** al producatorilor Abbott Vascular si Merit Medical, **desemnăm prin prezenta societatea:**

SC LIFE MED SRL
IDNO: 1014600035666
VAT: 0208964
Address: **str.Tudor Strisca 30 Chisinau, Moldova**

Ca reprezentant autorizat pe teritoriul Republicii Moldova, din numele producătorului Merit Medical.

Cu stima,
Director General
Udrescu Liviu Gheorghe

«LIFE MED» S.R.L. IDNO 1014600035666

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

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

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

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Abbott Ireland Ballytivnan Sligo Ireland	**ETO Sterilization**
Abbott Vascular International BVBA Park Lane Culliganlaan, 2B 1831 Diegem Belgium	**EU Representative**
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen Netherlands	**Distribution** **Labelling** **Packaging**
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	**Design** **Development** **E beam Sterilization** **Manufacture**

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Abbott Vascular 3885 Bohannon Drive Menlo Park CA 94025 USA	**Design** **Development** **Distribution** **Manufacture**
Abbott Vascular 52 Calle, 3, B31, Coyol Free Zone El Coyol Alajuela Costa Rica	**Manufacture**
Abbott Vascular Building PR-17, Road #2 km. 58.0 Cruce Davila Barceloneta 00617 Puerto Rico	**Manufacture**
Abbott Vascular Cashel Road Clonmel Tipperary Ireland	**Manufacture**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ «LIFE MED» S.R.L. IDNO 1014600035685 REPUBLICA MOLDOVA, mun. CHIȘINĂU

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**
Date: **13 July 2016**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

Subcontractor:	***Service(s) supplied***
Abbott West Distribution Center 42301 Zevo Drive Temecula California 92590 USA	**Distribution** **Manufacture**
Acme Monaco 75 Winchell Drive New Britain CT 06052 USA	**Manufacture**
Ad)medes Schuessler GmbH Rastatter Strasse 15 75179 Pforzheim Germany	**Manufacture**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1, C1, E1, E2, F2, G1 (Local A, B, C, G, H) La Mesa Tijuana, 22116 Mexico	**Manufacture**
Availmed S.A. de C.V. C. Industrial Lt. 001 Mz.105 No. 20905 Int. A Col. Cd. Industrial Tijuana Baja California 22444 Mexico	**Manufacture**
LEONI Studer AG Hogenweidstrasse 2+4 CH-4658 Däniken Switzerland	**E beam Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Nitinol Devices and Components, Inc. Costa Rica, S.R.L Coyol Free Zone Building B14 and B15 El Coyol, Alajuela Costa Rica	**Manufacture**
Nitinol Devices and Components, Inc 47533 Westinghouse Drive Fremont CA 94539 USA	**Manufacture**
Parter Sterilization Services LLC 17115 Kingsvew Ave Carson CA 90746 USA	**ETO Sterilization**

SOCIETATEA CU RĂSPUNDERE LIMITATĂ 2 «LIFE MED» S.R.L. IDNO 1014600035666 REPUBLICA MOLDOVA, mun. CHIȘINĂU

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**
Date: **13 July 2016**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

Subcontractor:	Service(s) supplied
Rose Technologies 1440 Front Avenue NW Grand Rapids Michigan 49504 USA	Manufacture
Sterigenics Costa Rica S.R.L., Zona Franca PROPARK Calle Principal, Edificio 10 El Coyol Alajuela Costa Rica	ETO Sterilization
Sterigenics Germany GmbH Kasteler Strasse 45 65203 Wiesbaden Germany	ETO Sterilization

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**
Sterigenics US, LLC 2400 Airport Road Santa Teresa New Mexico 88008 USA	**ETO Sterilization**
Sterigenics US, LLC 4900 South Gifford Avenue Los Angeles CA 90058 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	**E beam Sterilization**
Synergy Health AST, SRL B16, Street 4, Avenue 0 El Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**E beam Sterilization**
Synergy Health Ireland Ltd. IDA Business & Technology Park Sragh Industrial Estate Tullamore, Co. Offaly Ireland	**E beam Sterilization** **ETO Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 510108**

Date: **13 July 2016**

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

Subcontractor:	Service(s) supplied
Teleflex Medical OEM 50 Plantation Drive Jaffrey NH 03452 USA	Manufacture

SOCIETATEA CU RASPUNDERE LIMITATA 2 REPUBLICA MOLDOVA «LIFE MED» S.R.L. IDNO 1014600035666 mun. CHISINAU

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