

# 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.

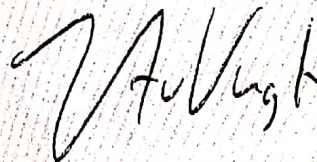
This certificate is valid until: 14 December 2023  
Issued for the first time: 1 July 2014

Revised: 21 December 2018  
Reissued: 14 December 2018

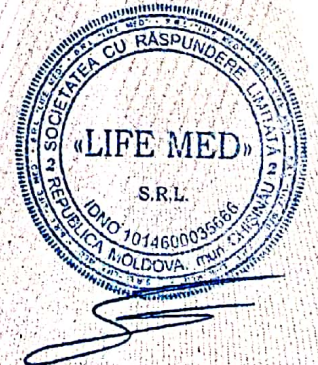
DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager



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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 Coyal 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

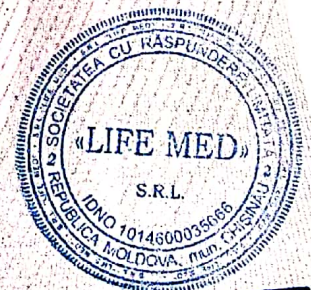
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B.T.M. Holtus  
Managing Director



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Certification Manager



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Issued to:

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

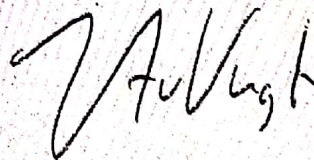
This certificate covers the following location(s):

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

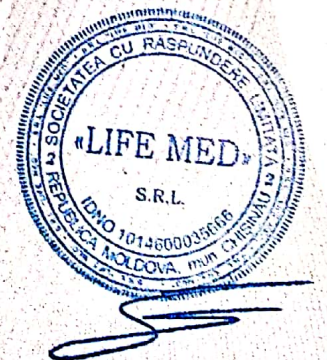
DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager



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Issued to:

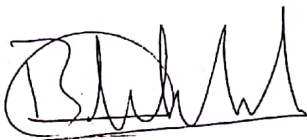
**Boston Scientific Corporation**  
 300 Boston Scientific Way  
 Marlborough, MA 01752  
 United States Of America

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

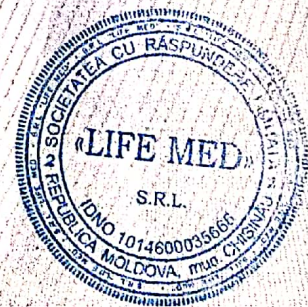
DEKRA Certification B.V.



B.T.M. Holtus  
 Managing Director



J.A. van Vugt  
 Certification Manager




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 T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

**sc Medical Devices & Diagnostics s.r.l.**

Adresa: Drumul Valea Furcii nr 111C, sector 6, Bucuresti

Tel/fax: +4021 3148044; email: [office@mdd.ro](mailto:office@mdd.ro); web: [www.mdd.ro](http://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**

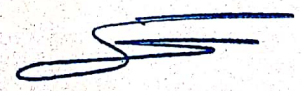
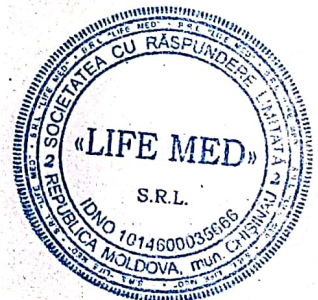
IDNO: 1014600035666

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



A handwritten signature in blue ink.



**sc Medical Devices & Diagnostics s.r.l.**

Adresa: Drumul Valea Furcii nr 111C, sector 6, Bucuresti

Tel/fax: +4021 3148044; email: [office@mdd.ro](mailto:office@mdd.ro); web: [www.mdd.ro](http://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 Moldova Str.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**

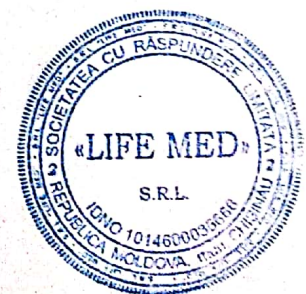
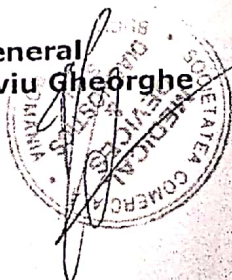
IDNO: 1014600035666

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





## 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:

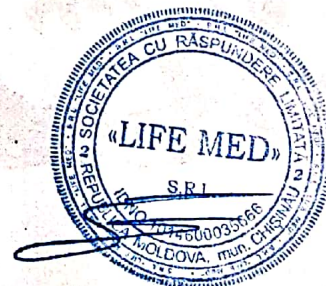
**The design, development and manufacture of coronary and peripheral dilation catheters, stent systems, including covered stents, drug eluting stents, Bioresorbable Vascular Scaffold (BVS) Systems, carotid and peripheral stent systems, embolic protection systems, arterial vessel closure devices and the 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**

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Page 1 of 1

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.



## EC Certificate - Full Quality Assurance System

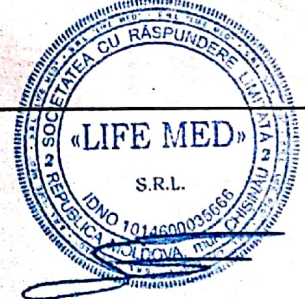
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### 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**

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



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## EC Certificate - Full Quality Assurance System

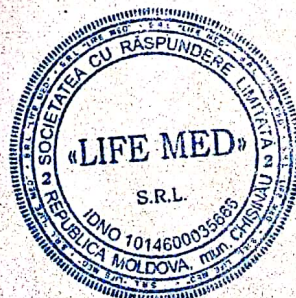
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### 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, Coyoil Free Zone El Coyoil 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



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## EC Certificate - Full Quality Assurance System

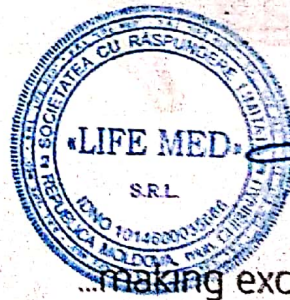
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### 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

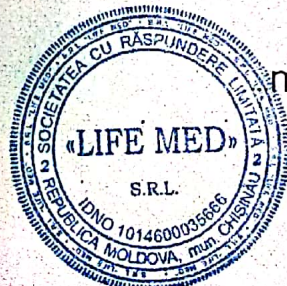
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### 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**

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



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# bsl.



## EC Certificate - Full Quality Assurance System

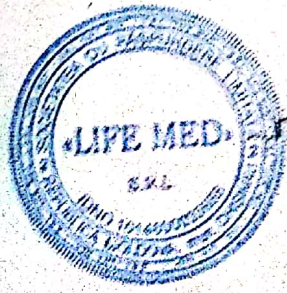
Directive 93/42/EEC on Medical Devices, Annex II excluding Section A

### 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**  
**3700 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 PROPARC Calle Principal, Edificio 10 El Croyal 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

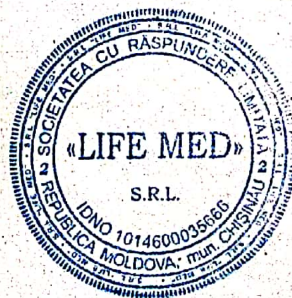
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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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

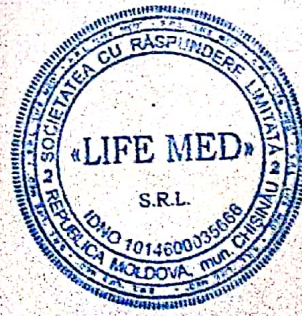
Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

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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 Coyal Free Zone 20102 El Coyal 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

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

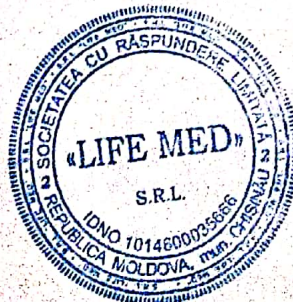
Certificate No: **CE 510108**  
Date: **13 July 2016**  
Issued To: **Abbott Vascular**  
**3200 Lakeside Drive**  
**Santa Clara**  
**California**  
**95054**  
**USA**

**Subcontractor:**

**Service(s) supplied**

Teleflex Medical OEM  
50 Plantation Drive  
Jaffrey  
NH 03452  
USA

**Manufacture**



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