EC CERTIFICATE

Number: 2107788CE18

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 16 May 2013

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: 16 May 2024
Issued for the first time: 16 May 2013
Reissued: 16 May 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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: 2107788CE18

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Guide wires for PTCA and PTA

Issued to:

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

This certificate covers the following product(s):

ASAHI PTCA Guide Wire			
Catalog No.	Product Name	Catalog No.	Product Name
APW14R009S	Fielder XT-A	APW14R005S	Fielder XT-R
APW14R309S	Fielder XT-A 300cm	APW14R305S	Fielder XT-R 300cm

Initial date: 16 May 2013
Revision date: 9 May 2016

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

Tıbbi Cihazlar K.Y.S.
TS EN ISO/IEC 17021
AB-0127-YS

TÜRKAK BDS NO
YS-6266-6564

NOTICE BELGELENDİRME MUAYENE ve DENETİM HİZMETLERİ A.Ş.

Hereby certifies that

Shunmei Medical Co., Ltd

With the addresses below:

Address : Head Office : R401 of building B, No.8 of 1st Jinlong Road, Baolong Industrial Zone, Longgang District, Shenzhen 518116, Guangdong, China
Factory : Yifa 3rd road, Yifa Industrial Zone, Pingtan Town, Huiyang District, Huizhou, Guangdong, China

has implemented a quality management system according to

EN ISO 13485:2016

The scope of this QMS includes:

Design & development, manufacturing and sales of medical devices: Guiding Catheter, Hydrophilic Coated Guide Wire, PTCA Guide Wire, Balloon Dilatation Catheter, Angiographic Catheter, Central Venous Catheter Kit, Introducer Sets, Hemodialysis Catheter kits, Hemostasis Valve Set, Guidewires, Introducer Needle, Disposable Pressure Transducers, Connecting Tubing, Angiographic Syringes, Drainage Catheter Kit, Cervical Ripening Balloon, Ureteral Stent Set, Percutaneous Nephrostomy Sets, Postpartum Balloon with Rapid Instillation Components, Dose Control Syringe, Stopcocks, Needle-free Connector, Manifold Kit, Manifolds, Balloon Inflation Devices, TR-closure Band

Certificate Number	:	**ISO.MED.0017.02.2019**
Issue Date	:	**11.02.2019**
Validatity Date	:	**10.02.2022**
Revision	:	**02**
Revision Date	:	**16.04.2019**

Approved by
Özlem VİCDAN AKDAĞ
Chairman of the Board
Signature

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.
Esentepe Mahallesi Milangaz Cd. No:75/A/92 Kartal İstanbul Türkiye
Tel: 00 90 216 504 16 98 – e-posta: info@notice.com.tr

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, femoral 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):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2006-08-01** Date: **2017-12-22** Expiry Date: **2020-10-16**

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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:	**2017-12-22**
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 The Netherlands	**Distribution** **Labelling** **Packaging**
Abbott Vascular 26531 Ynez Road Temecula California 92591 USA	**Design** **Development** **E beam Sterilization** **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:	**2017-12-22**
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	**Design** **Development** **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:	**2017-12-22**
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:	**2017-12-22**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

Subcontractor:	**Service(s) supplied**
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**
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**

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:	**2017-12-22**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

Subcontractor:	**Service(s) supplied**
Novartis Pharma AG Lichtstrasse 35 Basel CH-4056 Switzerland	**Crucial Supplier**
Parter Sterilization Services LLC 17115 Kingsview Ave Carson CA 90746 USA	**ETO Sterilization**
Rose Technologies 1440 Front Avenue NW Grand Rapids Michigan 49504 USA	**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:	**2017-12-22**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

Subcontractor:	**Service(s) supplied**
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**
Sterigenics UK Limited Cotes Park Estate Somercotes Alfreton DE55 4NJ United Kingdom	**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:	**2017-12-22**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

Subcontractor:	**Service(s) supplied**
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**
Sterigenics US, LLC 7695 Formula Place San Diego California 92121 USA	**E beam Sterilization**

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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

List of Significant Subcontractors

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

Certificate No:	**CE 510108**
Date:	**2017-12-22**
Issued To:	**Abbott Vascular** **3200 Lakeside Drive** **Santa Clara** **California** **95054** **USA**

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

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 510108**
Date: **2017-12-22**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

Date	Reference Number	Action
01 August 2006	4068482	First Issue based on CE 00946.
13 March 2007	4941821	Isotron Ireland, Ltd added to the list of significant subcontractors.
15 November 2007	7104034	Addition of Abbott Ireland (Galway) to the list of significant subcontractors. Addition of design and development of services supplied by Temecula.
01 August 2008	7200338	Addition of Abbott Vascular, Murrieta and Abbott Vascular, Barceloneta to list of significant subcontractors for manufacturing activities. Removal of Abbott Vascular, Dorado facility.
18 February 2009	7292729	Transfer of product families from Abbott Vascular, Vascular Solutions FQA certificate CE 525963. Remove Business Unit name (Cardiac Therapies) from the 'issued to' address and the Abbott Vascular, Murrieta facility address in the list of subcontractors. Addition of AD)MEDES Schuessler GmbH to list of significant subcontractors for manufacturing activities.
20 April 2010	7510769	Addition of Creganna-Tactx Medical to list of significant subcontractors for manufacturing activities and addition of Abbott Vascular International BVBA as EU Authorized Representative.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 510108**

Date: **2017-12-22**

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

Date	Reference Number	Action
12 October 2010	7581791	Renewal of certification Removal of Sterigenics (Salt Lake City), Abbott Ireland (Galway) and Isotron Ireland as significant subcontractors. Remove Abbott Vascular Sterilization from Clonmel manufacturing site. Addition of Sterigenics (New Mexico) as significant subcontractor. Removal of atherctomy catheters and motor drive units from the scope. Redefine stents as stent systems. Addition of Abbott West Distribution Center and Abbott Vascular Devices Holland B.V. as a significant subcontractor.
10 November 2011	7765633	Addition of LEONI Studer Hard AG to list of significant subcontractors for E beam sterilization.
13 December 2011	7766500	Addition of the Abbott Vascular Manufacturing Site in Alajuela, Costa Rica as a significant subcontractor.
31 May 2012	7804693	Addition of Synergy Health Ireland Ltd as a significant subcontractor for e-beam sterilization. Name of subcontractor Abbott Vascular Devices Holland B.V. changed to Abbott Vascular Netherlands B.V. and address updated. Administrative changes on certificate.
19 September 2012	7903213	Addition of Accellent as significant subcontractor for TREK family. Addition of Abbott Vascular Costa Rica Main Building as significant subcontractor for manufacturing.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 510108**
Date: **2017-12-22**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

Date	Reference Number	Action
21 December 2012	7911227	Addition of Abbott (Nutritional) Ireland Sligo to the list of significant subcontractors for the sterilization. Scope updated to include "including covered stents".
02 July 2013	7991114	Removal of Abbott Vascular - Alajuela Costa Rica, as a significant subcontactor. Change name of subcontractor from LEONI Studer Hard AG to LEONI Studer AG. Reclassify Funnel Introducer, Guide Wire Introducer, Duostat Rotating Hemostatic Valve, Rotating Hemostatic Valve, Guide Wire Introducer Accessory Kit and Guide Wire Accessory Kit with CoPilot from Class IIa to Class I (Sterile).
May 28, 2014	8164752	Addition of NovoSci and Sterigenics in Wiesbaden for the service of ETO sterilization, Synergy Health in Costa Rica for the service of E-beam sterilization and Availmed S.A. de C.V. for service of manufacturer due to several product transfers.
05 February 2015	8268209	Update to add Drug Eluting Stents to the scope. Addition of significant subcontractors OK International, LTD and Sterigenics UK Limited.
31 March 2015	8283470	Addition of Vessel Closure Devices to the scope of certification as part of a transfer from the Abbott Vascular Redwood City facility. Addition of significant subcontractors Teleflex Medical and Acme Monoco for manufacture and Synergy Health Ireland Ltd for EO Sterilization.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 510108**
Date: **2017-12-22**
Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

Date	Reference Number	Action
13 April 2015	8296689	Addition of Bioresorbable Vascular Scaffold (BVS) Systems to the scope of certification.
08 July 2015	8359594	Addition of Sterigenics Costa Rica S.R.L. as a significant subcontractor for ETO sterilization.
07 September 2015	8411826	Renewal of certification. Removal of subcontractors: Accellent, Inc., Creganna, NovoSci Corp and OK International, LTD. Removal of Abbott Vascular Murrieta site: facility closed down. Typo correction (LEONI Studer AG address, Sterigenics names).
19 December 2015	8427566	Scope extension to include the MitraClip NT System under Abbott Vascular's Quality System.
13 July 2016	8558860	Removal of "coronary and peripheral guiding catheters" from scope of certification and the addition of Availmed S.A. de C.V. Baja California location as significant subcontractor.
Current	8863184	Scope change from "Arterial" to "Femoral" for vessel closure devices. Removal of Availmed in La Mesa, Tijuana, Mexico for manufacturing services, and LEONI in Switzerland for Ebeam Sterilization. Addition of NOVARTIS as a crucial supplier. Add design and development services to Abbott in Clonmel, Ireland.

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 – II – III

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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:

- Disposable Pressure Transducers
- Hemodialysis Catheter Kits
- Connecting Tubing
- Introducer Sets
- Guide Wires
- Hemostasis Valve Set
- Ureteral Stent Set
- Introducer Needle
- Angiographic Syringe
- Closed Suction Kit
- Drainage Catheter
- Tracheostomy Tube
- Percutaneous Nephrostomy Sets
- Cervical Ripening Balloon
- Postpartum Balloon with Rapid Instillation Components

Notified Body

Date: 2017-08-29

X. Ren

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
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

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Stopcocks
- Manifolds
- Balloon Inflation Devices
- Dose Control Syringe
- Manifold Kit
- Angio-closure Pad
- TR-Closure Band
- Needle-free Connector

Sites included:

Floor1-floor3 of building C, No.8 of 1st Jinlong Road,
Baolong Industrial Zone, LongGang District,
518116 Shenzhen, Guangdong, China

Huizhou branch of Shunmei Medical Co., Ltd
Yifa industrial zone, Dushi village, Pingtan town,
HuiYang District, HuiZhou City, China

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2017-08-29

X. Ren

CERTIFICATE

EC Certificate No. 1434-MDD-389/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meril Life Sciences Pvt. Ltd.

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

for the design, manufacture and final inspection of

medical devices, class III

BioMime™ Sirolimus Eluting Coronary stent system

List of medical devices covered by this certificate is given in the Annex no. 1, 2, 3 , 4, 5 to the EC Design-examination Certificate No. 1434-MDD-390/2019

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.07.2019 to 13.11.2022

The date of issue of the Certificate: 26.07.2019

CE 1434

Mgr Anna Wyroba
Vice-President

Application No: 214/2019
Module H

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

Certificate No. **1434-MDD-389/2019**
Issued under the Contract No. **MD-131/2019**
Bears the PCBC hologram
Warsaw, 26/07/2019

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
261407-2018-CE-IND-NA-PS	**PRJC-517914-2015-MSL-IND**	**03 June 2023**

This is to certify that the quality system of:

Meril Life Sciences Private Limited
Muktanand Marg, Chala, Vapi,
Gujarat,
India-396191

For design, production and final product inspection/testing of:

PTCA Balloon Dilatation Catheters

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 25 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **261407-2018-CE-IND-NA-PS**

Project No.: **PRJC-517914-2015-MSL-IND**

Valid Until: **03 June 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	This certificate is traceable to the old certificate no. 11067-2017-CE-IND-NA-PS Rev. 0.0 & 11128-2017-CE-IND-NA-PS Rev. 0.0 and Reissued with Recertification	2018-06-03

Products covered by this Certificate:

Product Description	Product Name	Class
PTCA Balloon Dilatation Catheters	• Xpedient™ Rx PTCA Balloon Dilatation Catheter (Sterile and Non-Sterile)	III*

Catalogue Numbers

Diameters (mm)	Lengths (mm)													
	6	9	12	14	15	17	20	25	30	33	38	41	45	49
1.25	XPD 12506	XPD 12509	XPD 12512	-	XPD 12515	-	-	-	-	-	-	-	-	-
1.50	-	XPD 15009	XPD 15012	-	XPD 15015	-	-	-	-	-	-	-	-	-
2.00	-	XPD 20009	XPD 20012	XPD 20014	XPD 20015	XPD 20017	XPD 20020	XPD 20025	XPD 20030	XPD 20033	XPD 20038	XPD 20041	XPD 20045	XPD 20049
2.25	-	XPD 22509	-	XPD 22514	-	XPD 22517	XPD 22520	XPD 22525	XPD 22530	XPD 22533	XPD 22538	XPD 22541	XPD 22545	XPD 22549
2.50	-	XPD 25009	-	XPD 25014	-	XPD 25017	XPD 25020	XPD 25025	XPD 25030	XPD 25033	XPD 25038	XPD 25041	XPD 25045	XPD 25049
2.75	-	XPD 27509	-	XPD 27514	-	XPD 27517	XPD 27520	XPD 27525	XPD 27530	XPD 27533	XPD 27538	XPD 27541	XPD 27545	XPD 27549
3.00	-	XPD 30009	-	XPD 30014	-	XPD 30017	XPD 30020	XPD 30025	XPD 30030	XPD 30033	XPD 30038	XPD 30041	XPD 30045	XPD 30049
3.50	-	XPD 35009	-	XPD 35014	-	XPD 35017	XPD 35020	XPD 35025	XPD 35030	XPD 35033	XPD 35038	XPD 35041	XPD 35045	XPD 35049
4.00	-	XPD 40009	-	XPD 40014	-	XPD 40017	XPD 40020	XPD 40025	XPD 40030	XPD 40033	XPD 40038	XPD 40041	XPD 40045	XPD 40049
4.50	-	XPD 45009	-	XPD 45014	-	XPD 45017	XPD 45020	XPD 45025	XPD 45030	XPD 45033	XPD 45038	XPD 45041	XPD 45045	XPD 45049

EC Certificate
Full Quality Assurance System

Certificate No.: **261407-2018-CE-IND-NA-PS**
Project No.: **PRJC-517914-2015-MSL-IND**
Valid Until: **03 June 2023**

- Mozec™ – Rx PTCA Balloon Dilatation Catheter (Sterile and Non-Sterile) (Second brand name of Xpedient™ – Rx PTCA Balloon Dilatation Catheter)

Catalogue Numbers														
Diameters (mm)	Lengths (mm)													
	6	9	12	14	15	17	20	25	30	33	38	41	45	49
1.25	MOZ 12506	MOZ 12509	MOZ 12512	-	MOZ 12515	-	-	-	-	-	-	-	-	-
1.50	-	MOZ 15009	MOZ 15012	-	MOZ 15015	-	-	-	-	-	-	-	-	-
2.00	-	MOZ 20009	MOZ 20012	MOZ 20014	MOZ 20015	MOZ 20017	MOZ 20020	MOZ 20025	MOZ 20030	MOZ 20033	MOZ 20038	MOZ 20041	MOZ 20045	MOZ 20049
2.25	-	MOZ 22509	-	MOZ 22514	-	MOZ 22517	MOZ 22520	MOZ 22525	MOZ 22530	MOZ 22533	MOZ 22538	MOZ 22541	MOZ 22545	MOZ 22549
2.50	-	MOZ 25009	-	MOZ 25014	-	MOZ 25017	MOZ 25020	MOZ 25025	MOZ 25030	MOZ 25033	MOZ 25038	MOZ 25041	MOZ 25045	MOZ 25049
2.75	-	MOZ 27509	-	MOZ 27514	-	MOZ 27517	MOZ 27520	MOZ 27525	MOZ 27530	MOZ 27533	MOZ 27538	MOZ 27541	MOZ 27545	MOZ 27549
3.00	-	MOZ 30009	-	MOZ 30014	-	MOZ 30017	MOZ 30020	MOZ 30025	MOZ 30030	MOZ 30033	MOZ 30038	MOZ 30041	MOZ 30045	MOZ 30049
3.50	-	MOZ 35009	-	MOZ 35014	-	MOZ 35017	MOZ 35020	MOZ 35025	MOZ 35030	MOZ 35033	MOZ 35038	MOZ 35041	MOZ 35045	MOZ 35049
4.00	-	MOZ 40009	-	MOZ 40014	-	MOZ 40017	MOZ 40020	MOZ 40025	MOZ 40030	MOZ 40033	MOZ 40038	MOZ 40041	MOZ 40045	MOZ 40049
4.50	-	MOZ 45009	-	MOZ 45014	-	MOZ 45017	MOZ 45020	MOZ 45025	MOZ 45030	MOZ 45033	MOZ 45038	MOZ 45041	MOZ 45045	MOZ 45049

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 261408-2018-CE-IND-NA-PS

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Meril Life Sciences Pvt. Ltd. Muktanand Marg, Chala, Vapi, Gujarat, India-396191

EU Representative

Obelis S.A. Brussels, Belgium

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
261407-2018-CE-IND-NA-PS	**PRJC-517914-2015-MSL-IND**	**03 June 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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

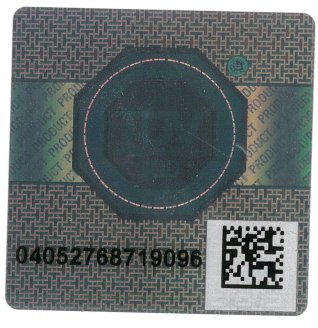
Product Category(ies):

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

TÜV®

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ 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

Facility(ies):

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

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

TÜV®

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: ASAHI INTECC CO., LTD.
3-100 Akatsuki-cho,
Seto,
Aichi
489-0071
Japan

朝日インテック株式会社
〒489-0071
愛知県
瀬戸市
暁町3番地100

Holds Certificate No: MD 696055

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacturing, EtO sterilization and sales of Catheters and Guidewires.
Manufacturing control and sales of Electrosurgical snares for use in endoscopy.
カテーテル及びガイドワイヤの設計、製造、エチレンオキサイド滅菌及び販売
内視鏡用電気外科用スネアの製造管理及び販売

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-06-28
Latest Revision Date: 2018-12-04

Effective Date: 2018-12-04
Expiry Date: 2021-12-03

...making excellence a habit.™

Certificate No: MD 696055

Location	Registered Activities
ASAHI INTECC CO., LTD. Medical(1) 3-100 Akatsuki-cho, Seto, Aichi 489-0071 Japan 朝日インテック株式会社 メディカル(1) 〒489-0071 愛知県 瀬戸市 暁町3番地100	Design, manufacturing, EtO sterilization and sales of Catheters and Guidewires. Manufacturing control and sales of Electrosurgical snares for use in endoscopy. カテーテル及びガイドワイヤの設計、製造、エチレンオキサイド滅菌及び販売 内視鏡用電気外科用スネアの製造管理及び販売
ASAHI INTECC CO., LTD. Medical(2) 3-99 Akatsuki-cho, Seto, Aichi 489-0071 Japan 朝日インテック株式会社 メディカル(2) 〒489-0071 愛知県 瀬戸市 暁町3番地99	Design, manufacturing and sales of Catheters and Guidewires. Manufacturing control and sales of Electrosurgical snares for use in endoscopy. カテーテル及びガイドワイヤの設計、製造及び販売 内視鏡用電気外科用スネアの製造管理及び販売
ASAHI INTECC CO., LTD. Technical Center 3-102 Akatsuki-cho, Seto, Aichi 489-0071 Japan 朝日インテック株式会社 テクニカルセンター 〒489-0071 愛知県 瀬戸市 暁町3番地102	Design, manufacturing and sales of Catheters and Guidewires. Manufacturing control and sales of Electrosurgical snares for use in endoscopy. カテーテル及びガイドワイヤの設計、製造及び販売 内視鏡用電気外科用スネアの製造管理及び販売

Original Registration Date: 2018-06-28
Latest Revision Date: 2018-12-04

Effective Date: 2018-12-04
Expiry Date: 2021-12-03

Certificate No: MD 696055

Location	Registered Activities
ASAHI INTECC CO., LTD. Tokyo Office Shinagawa Front Bldg. 2-3-13 Konan, Minato-ku, Tokyo 108-0075 Japan 朝日インテック株式会社 東京営業所 〒108-0075 東京都 港区 港南2-3-13 品川フロントビル	Sales of Catheters, Guidewires and Electrosurgical snares for use in endoscopy. カテーテル、ガイドワイヤ及び内視鏡用電気外科用スネアの販売

Original Registration Date: 2018-06-28
Latest Revision Date: 2018-12-04

Effective Date: 2018-12-04
Expiry Date: 2021-12-03

3Teks Tekstil Gıda İthalat İhracat San. ve Ticaret Ltd. Şti.

Merkez:2. Organize Sanayi Bölgesi No:1 Başpınar / Gaziantep / Türkiye
T: +90 (342) 337 24 16 - 17 - 18 - 19 **F:** +90 (342) 337 21 11
İstanbul Ofis **T:** +90 (216) 384 24 48 - 49 **F:** +90 (216) 384 24 57
Ankara Ofis **T:** +90 (312) 442 15 79 **F:** +90 (312) 442 15 89
www.3teks.com.tr info@3teks.com.tr

Manufacturer:	*European Representative:*	*Rev. Date:25.02.2015 Rev.No:14*
3teks Tekstil Gıda İth. İhr. San. Ve Tic. Ltd. Şti. 2. Org. San. Böl. No: 1 Başpınar / Gaziantep	Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands	*Document id* **TDS–08**

European Declaration of Conformity to the Medical Device Directive, 93/42/EEC

CE
1008

Product Name	:	Disposable Sterile Surgical Drapes, Gowns And Packs
Description	:	Intended use of surgical drapes and gowns to protect doctor and patient during operation from bacterial infections.
Sterile	:	Yes
Classification / Rule *(acc. to MDD – Annex IX)*	:	Class I Sterile / Rule 1
Conformity Assessment Route	:	According to Annex V+VII of the Directive 93/42/EEC on Medical Device Product Quality Assurance

Declaration :

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer. And we declare these products' shell life is if sterilize with ethylene oxide 3 years, if sterilize with radiation 5 years.
Harmonised standarts attached on pages below.

As required by the above mentioned Directive, this Declaration is supported by:

EC Certificate No : OD 69246606 0001

QSys Certificate No : OX 69246608 0001 (EN ISO 13485:2012+AC:2012)

01 100 1320378 (ISO 9001:2008)

Notified Body : TÜV Rheinland InterCert Kft.
H-1132 Budapest, Vaci ut 48/A-B

Date : 11.06.2015
Signature : General Manager

3 TEKS TEKSTİL
Gıda İth. İhr. San. ve Tic. Ltd. Şti.
2.Org.San.Böl.Muammer Güler
Bulvarı No:1 Gaziantep/Turkey
Şahinbey V.D. 001 051 5422

TÜVRheinland CERT ISO 9001 EN ISO 13485 | CE1008 | TSE TS EN 13795+A1 | TÜRKAK | TSEK

3Teks Tekstil Gıda İthalat İhracat San. ve Ticaret Ltd. Şti.

Merkez:2. Organize Sanayi Bölgesi No:1 Başpınar / Gaziantep / Türkiye
T: +90 (342) 337 24 16 - 17 - 18 - 19 **F:** +90 (342) 337 21 11
İstanbul Ofis **T:** +90 (216) 384 24 48 - 49 **F:** +90 (216) 384 24 57
Ankara Ofis **T:** +90 (312) 442 15 79 **F:** +90 (312) 442 15 89
www.3teks.com.tr info@3teks.com.tr

HARMONISED STANDARTS

EN ISO 9001:2008
Quality management systems – Requirements
EN ISO 13485:2012+AC :2012
Quality Management Systems – Medical Devices System Requirements for regulatory purpose.
EN 980:2008
Graphical symbols for use in the labeling of medical devices
EN 1041:2008
Information supplied by the manufacturer with medical devices
EN ISO 14971:2012
Medical Devices – Application of Risk Management to Medical Devices
EN ISO 14644-1:1999
Clean rooms and associated controlled environments Part 1: Classification of air cleanliness
EN ISO 14644-2:2000
Clean rooms and associated controlled environments - Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
EN ISO 14644-3:2005
Clean rooms and associated controlled environments - Part 3: Test methods
EN ISO 14644-4:2001
Clean rooms and associated controlled environments - Part 4: Design, construction and start-up
EN ISO 14644-5:2004
Clean rooms and associated controlled environments - Part 5: Operations
EN 556-1:2001
EtO Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices.
EN 11607-1:2006
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN 11607-2:2006
Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11135-1:2007
Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11135-2:2008
Sterilization of health care products -- Ethylene oxide -- Part 2: Guidance on the application of ISO 11135-1
EN ISO 10993-1:2009
Biological Evaluation of Medical Devices Part 1: Evaluation

3Teks Tekstil Gıda İthalat İhracat San. ve Ticaret Ltd. Şti.

Merkez:2. Organize Sanayi Bölgesi No:1 Başpınar / Gaziantep / Türkiye
T: +90 (342) 337 24 16 - 17 - 18 - 19 **F:** +90 (342) 337 21 11
İstanbul Ofis **T:** +90 (216) 384 24 48 - 49 **F:** +90 (216) 384 24 57
Ankara Ofis **T:** +90 (312) 442 15 79 **F:** +90 (312) 442 15 89
www.3teks.com.tr info@3teks.com.tr

and testing

EN ISO 10993-7:2008
Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals

EN 11737-1:2006
Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

EN 11737-2:2009
Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

ISO 14698-1:2003
Cleanrooms and associated controlled environments -- Biocontamination control -- Part 1: General principles and methods

ISO 14698-2:2003
Cleanrooms and associated controlled environments -- Biocontamination control -- Part 2: Evaluation and interpretation of biocontamination data

EN ISO 13795+A1
Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

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

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

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

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

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

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

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

CERTIFICATE

kiwa

3TEKS TEKSTİL GIDA İTHALAT İHRACAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Başpınar (Organize) OSB Mahallesi 2. Organize Sanayi Bölgesi Vali Muammer Güler Bulvarı No:5/0 Şehitkamil - Gaziantep - Turkey

with a scope of

Production, Distrubition and Sale Sterile Disposable Surgery Gowns, Sterile Disposable Surgery Drapes, Sterile Disposable Surgery Packs, Storing and Sale Medical Packaging Sterilization Packaging Materials and Sterilization with Ethylene Oxide According to EN ISO 11135"

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.3" "7.5.3" "7.5.4" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 11185
Initial Certification Date	: 26 February 2019
Certification Date	: 26 February 2019
Expiration Date	: 25 February 2022

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-6A23-39FD

Last Modified: 26 February 2019 - R 00

Management System Certificate

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
242566-2017-AQ-IND-NA-PS Rev. 2.0	**PRJC-517914-2015-MSL-IND**	**17 July 2008**	**17 July 2020**

This is to certify that the management system of:

Meril Life Sciences Private Limited

Muktanand Marg, Chala, Vapi - 396191
Gujarat, India

Complies with the requirements of:

ISO 13485:2016 / NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design and Development, Manufacture, Distribution, Storage, Sales and Supply of Sterile and Non Sterile Drug Eluting and Bare Metal Vascular Stents and Stents Systems, Inflation Device, PTCA & PTA Balloon Dilatation Catheters, PTCA and PTA Guide Wires, Aspiration Catheters, Sinuplasty System, Occluder and Delivery Systems, Angiokit, Drug Eluting PTCA and PTA Balloon Dilatation Catheters, Drug Eluting Bioresorbable Vascular Scaffold System, Intra Aortic Balloon Catheters, Liquid Embolic System, Vascular Closure Device, Bare Metal and Drug Eluting Self Expanding Peripheral Stent System and Transcatheter and Surgical Heart Valve Systems.

Place and Date:
Høvik, 20 June 2019

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL PRESAFE AS

Bjørg Synnøve Nesgård

Bjørg Synnøve Nesgård

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA

Holds Certificate No: **FM 534441**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Please see scope page.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2008-09-05
Latest Revision Date: 2018-12-20

Effective Date: 2017-12-21
Expiry Date: 2020-12-20

...making excellence a habit.™

Certificate No: **FM 534441**

Registered Scope:

The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), occluding guidewires, guidewire insertion tools, introducer needles, trocars, hemodialysis catheters, obturators, sharps holders, kits, introducer devices, insertion devices, torque devices, waste disposal systems, flush devices, fluid administration/handling devices (including high and low pressure – tubing, manifolds, stopcocks, valves) and kits, dilators, hemostasis valves, pressure monitors and transducers (including electronic), drainage devices, contrast management devices (systems and kits), embolectomy devices, snare devices and accessories, inflation device (analog and digital), infusion devices, angiographic needles, compression devices, scalpels, syringes, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, endoscopic guidewires, balloon catheters, bipolar coagulation probes, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments, inflatable balloon tamps, endovascular stent grafts, RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.

Original Registration Date: 2008-09-05
Latest Revision Date: 2018-12-20

Effective Date: 2017-12-21
Expiry Date: 2020-12-20

Certificate No: **FM 534441**

Location	Registered Activities
Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan Utah 84095 USA	The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) including angiographic, angioplasty and other procedure kits/packs, angiographic catheters, vascular catheters, peripheral catheters, guiding catheters, guidewires (coated and uncoated), introducer needles, angiographic needles, trocars, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, inflation systems (analog and digital), scalpels, torque devices, tubing, manifolds/stopcocks, valves, syringes, waste disposal, tracheobronchial and esophageal stent systems (and accessories), biliary stent systems, balloon catheters, bipolar coagulation probes and all related accessories, stent positioning system intended for coronary or renal interventional procedures, peritoneal dialysis catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts and graft accessory component kits, and orthopedic surgical instruments , inflatable balloon tamps, endovascular stent grafts, and RF tumor ablation systems for orthopedic applications.
Merit Medical Ireland Ltd Parkmore Business Park West Galway Ireland	The design, development, manufacture, packaging and distribution of sterile medical devices (and associated accessories) for infusion, drainage angiography needles, analog inflation devices, occluding guidewires, guide wires (coated and uncoated), tubing, stopcocks, manifolds (including high pressure), angioplasty procedure packs containing guidewire insertion tools, hemostasis valves and torque devices, disposal depots, disposal pressure transducers, fluid administration and contrast management sets (with or without adaptors), insertion devices, torque devices, introducer needles, angiographic needles, obturators, temporary sharps holders, waste disposal basins, fluid administration, scalpels, flush devices, endovascular snare devices and accessories, peripheral catheters, orthopedic bone cement, bone cement delivery devices/accessories, biopsy Instruments and accessories, inflatable balloon tamps and RF tumor ablation systems for orthopedic applications and non-sterile customer specified components for minimally invasive medical devices.

Original Registration Date: 2008-09-05
Effective Date: 2017-12-21
Latest Revision Date: 2018-12-20
Expiry Date: 2020-12-20

Certificate No: **FM 534441**

Location	Registered Activities
Merit Medical Systems, Inc. 1375 West 8040 South West Jordan Utah 84088 USA	The manufacture and packaging of sterile medical devices including balloon catheters and compression devices.
Merit Holdings, Inc. Amerikalaan 42 6199 AE Maastricht-Airport The Netherlands	Customer service, labeling and distribution.
Merit Medical Systems, Inc. 14646 Kirby Drive Houston Texas 77047 USA	Design, development, manufacture, packaging, and distribution of sterile medical devices including catheters and guide catheters (braided and non-braided), (single and multipack), introducers (vascular and non-vascular), dilators (vascular and non-vascular), tracheobronchial and esophageal stent systems (and accessories), biliary stent systems and associated kits (single and multipack) for angiography, drainage, coronary and peripheral applications.
Merit Maquiladora México, S. DE R.L. DE C.V. Avenida Sor Juana Inés de la Cruz 19970 interior B, Edificio 2 Parque Industrial Frontera Tijuana, Baja California C.P. 22630 Mexico	The design, development, manufacture, packaging and distribution of sterile medical devices including infusion devices, catheter and guide catheters, fixation devices, vascular & non-vascular Introducers and dilators, scalpels, biopsy instruments and accessories, Waste disposal Systems, Sharps Holders, Fluid Administration/Handling devices (including High and Low Pressure ? Tubing, Manifolds, Compression Devices and Contrast Management devices (Systems and Kits).

Original Registration Date: 2008-09-05
Latest Revision Date: 2018-12-20

Effective Date: 2017-12-21
Expiry Date: 2020-12-20

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 South
Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636367**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for the medical device industry.

For and on behalf of BSI:

Chief Operating Officer Assurance - Americas

Original Registration Date: 2016-05-20
Effective Date: 2018-06-26
Latest Revision Date: 2018-06-26
Expiry Date: 2021-06-25

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