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

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 69002**

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

In respect of:

Cordis 6F 0.070" Vista Brite Tip® Guiding Catheters

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2002-08-19** Date: **2017-07-31** Expiry Date: **2022-08-18**

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EC Design-Examination Certificate

Supplementary Information to CE 69002

Issued To:

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Product:

General Designation: 670-XXX-XX
XXX – XXX – XXX
123 456 789

Number / Designation	**Limitation**
1 Outer Diameter (last digit of French Size)	Will always be 6 French
2,3 Lumen Size (last 2 digits in thousandths of an inch)	0.065-0.075 inches
4,5,6 Configuration 000-299 Standard (subassembly) design 300-599 Design variation 1 600-899 Design variation 2 900-999 Design variation 3 / Overflow	Odd numbers contain a side hole Even numbers do not contain a side hole
7,8 Length (last 2 digits in cm)	50-125 cm
In addition digits 8 or 9 may contain a single letter code. For example, E – Econopack L – Long Bright Tip N – Guiding catheter with an introducer	

Modified Standards: SMXXXX and SMXXXXX

First Issued: **2002-08-19** Date: **2017-07-31** Expiry Date: **2022-08-18**

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EC Design-Examination Certificate

Supplementary Information to CE 69002

Issued To:

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Certificate History

Date	Reference Number	Action
19 August 2002	EQ 10040583	First issue. Change of format of the Certificate product listing.
09 December 2003	EQ 10052521	The addition of Roden, The Netherlands to the list of Sterilization companies used. New format for the presentation of the catalogue numbers.
23 August 2004	EQ 10059974	Shelf Life extension to 3 years and revision of history to remove items prior to first issue under CE 69002.
31 March 2006	EQ 10078108	Changes to wildcards.
08 June 2007	EQ 10088941	Change in pouch heat seal coating from CR 27 (ex. Perfecseal) and 703 HSC (ex. Mangar) to PTH 025 (ex. Mangar).
01 August 2007	EQ 10089895	Add pouch with RLE004 PET/PE film PTH 034 heat seal coating, and Tyvek 1073B.
31 August 2007	EQ 10089893	Certificate renewal.
16 August 2012	10136333	Certificate renewal Modified Standards: SMXXXX and SMXXXXX added as they were inadvertently omitted when CE 69002 was split from CE 01110 under EQ 10040583.

First Issued: **2002-08-19** Date: **2017-07-31** Expiry Date: **2022-08-18**

EC Design-Examination Certificate

Supplementary Information to CE 69002

Issued To:

Cordis Corporation
14201 North West 60th Avenue
Miami Lakes
Florida
33014
USA

Certificate History

Date	Reference Number	Action
04 February 2016	10160465	Change affecting DuPont Tyvek 1073B packaging material – all product codes are affected.
Current	8763074	Certificate Renewal. Removed Envoy® Guiding Catheter from certificate scope and product catalogue.

First Issued: **2002-08-19** Date: **2017-07-31** Expiry Date: **2022-08-18**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 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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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.

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

TAM KALİTE

GÜVENCE BELGESİ

MERIL LIFE SCIENCES PVT. LTD.

firması

MUKTANAND MARG, CHALA, VAPI-396191. GUJARAT, HİNDİSTAN

adresinde

SİROLİMUS SALINIMLI BİYOEMİLEBİLİR VASKÜLER SCAFFOLD SİSTEMİ
(MERES100™ LINEAGE)

kapsamı için

93/42/AT – Tıbbi Cihaz Yönetmeliği
Tam Kalite Güvence Sistemi EK-II (Bölüm 4 Hariç)

gereklerine göre tetkik edilmiş ve belgelendirilmiştir.

Onaylanmış Kuruluş Numarası:	1783
Belge Veriliş Tarihi:	17.05.2019
Geçerlilik Tarihi:	17.05.2024
GMDN Kodu:	56304
Sınıflandırma:	Sınıf III
AT Tasarım İnceleme Belgesi Numarası:	1783-MDD-119
İnceleme Rapor Numarası:	1542-MDD-099/2018-01
Belge Değişiklik Tarihi / Nedeni:	-

Tıbbi Cihaz Yönetmeliği Ek II Bölüm 3'e göre Kalite Sisteminin Teknik Düzenleme / Uyumlaştırılmış Standard gereklerini karşıladığını gösteren, işbu belge ile Kuruluş; tetkiki yapılan kalite sistemi kapsamında, CE Uygunluk İşaretini, aşağıda gösterildiği şekilde iliştirme ve Onaylanmış Kuruluş numarasını kullanmaya yetkilidir. Onaylanmış Kuruluş Tıbbi Cihaz Yönetmeliğinin EK II, 5. bölümüne istinaden gerekli gözetimleri yapma hakkına sahiptir.
Bu belge kapsamında bulunan Sınıf III ürün(ler)ün CE işaretlemesi için, Tıbbi Cihaz Yönetmeliği EK-II, 4. Bölümüne göre düzenlenen Tasarım İnceleme Belgesi de gerekmektedir.

CE

Belge No: 1783 -MDD- 118

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * TURKISH STANDARDS INSTITUTION * DIRECTORATE OF DIRECTIVE

SEZAİ DOĞAN
Direktifler Müdürü
ANKARA Rev 00, 17/05/2019

Bu belge ancak TSE- Onaylanmış Kuruluş Numarası 1783 mührü ile geçerlidir.

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

CERTIFICATE OF FULL QUALITY ASSURANCE

MERIL LIFE SCIENCES PVT LTD

located at the address
MUKTANAND MARG CHALA VAPI-396191 GUJARAT INDIA

for the scope of

SIROLIMUS ELUTING BIORESORBABLE VASCULAR SCAFFOLD SYSTEM
(MERES100™ LINEAGE)

has been examined and certified to the requirements of

93/42/EEC – Medical Device Directive
Full Quality Assurance System Annex II (Excluding Section 4)

Notified Body Number:	1783
Date of Issue:	17.05.2019
Valid Until:	17.05.2024
GMDN Code:	56304
Classification:	Class III
EC Design Examination Certificate Number:	1783-MDD-119
Inspection Report Number:	1542-MDD-099/2018-01
Date / Reason of the Certificate Revision:	-

This certificate remarks that quality system meets requirements of the technical regulations / harmonized standards according to Medical Device Directive Annex II Section 3 and with this certificate the company is authorized to affix CE Mark, as shown below, and Notified Body Number on the products in the scope of the examined quality system. Notified Body has the right to carry out required surveillance audits according to Medical Device Directive Annex II Section 5.

For the CE marking of Class III product(s) in the scope of this certificate, EC Design Examination Certificate issued according to Medical Device Directive Annex II Section 4.

CE

Certificate Number: 1783 - MDD - 118

TÜRK STANDARDLARI ENSTİTÜSÜ DİREKTİFLER MÜDÜRLÜĞÜ
DIRECTORATE OF DIRECTIVES TURKISH STANDARDS INSTITUTION

SEZAİ DOĞAN
Director of Directives
ANKARA Rev 00, 17/05/2019

This certificate is valid only with the TSE Notified Body Number 1783 seal.

TÜRK STANDARDLARI ENSTİTÜSÜ

TURKISH STANDARDS INSTITUTION

AT TASARIM İNCELEME BELGESİ

(EC DESIGN EXAMINATION CERTIFICATE)

BELGE NO *(CERTIFICATE NO)*: 1783 – MDD- 119

Aşağıda adı ve adresi yazılı üreticinin tasarımı;

(design of the manufacturer)

MERIL LIFE SCIENCES PVT LTD

MUKTANAND MARG, CHALA, VAPI-396191 GUJARAT INDIA (Merkez Adres/*Head Office*)

MUKTANAND MARG, CHALA, VAPI-396191 GUJARAT INDIA (Üretim *Adresi*/*Manufacturer Address*)

93/42/AT – Tıbbi Cihaz Yönetmeliği (EK-II *(BÖLÜM* 4)) gereklerine göre incelenmiş ve belgelendirilmiştir.

Has been examined and certified according to 93/42/EEC Medical Device Directive (ANNEX II (Article 4))

SİROLİMUS SALINIMLI BİYOEMİLEBİLİR VASKÜLER SCAFFOLD SİSTEMİ
SIROLIMUS ELUTING BIORESORBABLE VASCULAR SCAFFOLD SYSTEM
(MERES100™ LINEAGE)

Onaylanmış Kuruluş No *Notified Body Number*:	**1783**
Belge Veriliş Tarihi *Date of Issue*:	**17.05.2019**
Belge Geçerlilik Tarihi *Valid Until*:	**17.05.2024**
Proje Kayıt No *Project Registration Number*:	**1542-18/12817, 1543-18/12823**
GMDN Kodu *GMDN Code:*	**56304**
Tam Kalite Güvence Belgesi No:	**1783-MDD-118**
Full Quality Assurance Certificate Number:	
Tasarım Dosyası Değerlendirme Rapor No:	**1542-MDD-099/2019-02**
Design Dossier Review Report Number:	
Belge Değişiklik Tarihi / Nedeni:	-
Date / Reason of the Certificate Revision	

Bu belge ekleriyle birlikte geçerlidir. Ekleriyle birlikte 4 sayfadır. *(This certificate is valid only with attached annex, if any 4 pages including this page)*

AT Tasarım İnceleme Sertifikası, Sınıf III ürünler için, Tam Kalite Güvence (EK-II Bölüm 4 Hariç) belgesinin bir parçasıdır.

For Class III products EC Design-Examination Certificate is part of the Full Quality Assurance Certificate (MDD Annex II Article 4 Excluded)

TÜRK STANDARTLARI ENSTİTÜSÜ * DİREKTİFLER MÜDÜRLÜĞÜ * TURKISH STANDARDS INSTITUTION * DIRECTORATE OF DIRECTIVES

SEZAİ DOĞAN
Direktifler Müdürü
Director of Directives
Ankara Rev00, 17/05/2019

Bu belge ancak TSE- Onaylanmış Kuruluş Numarası 1783 mührü ile geçerlidir.
This certificate is only valid if sealed with "TSE- European Notified Body Number 1783".

AT TASARIM İNCELEME BELGESİ EKİ
ANNEX TO THE EC DESIGN EXAMINATION CERTIFICATE
BELGE NO *(CERTIFICATE NO)*: 1783 – MDD –119

Ürünün Kullanım Amacı *(Intended Use of the Product)*

MeRes100™ Lineage BRS perkütan transluminal koroner anjiyoplasti ve scaffold prosedürlerine elverişli hastaların nativ koroner arterlerinde de novo ve stent için restenotik lezyonlara bağlı semptomatik iskemik hastalık gelişmesi durumda koroner luminal çapın geliştirilmesi için endikedir.
MeRes100™ Lineage BRS is indicated for improving the coronary luminal diameter in patients with symptomatic ischemic disease due to de novo and in-stent restenotic lesions in native coronary arteries in patients eligible for percutaneous transluminal coronary angioplasty (PTCA) and scaffolding procedure.

Ürün Tipi *(Product Type)* :

MeRes100™ Lineage BRS aşağıdakilerden oluşmaktadır-

- Poli-L-Laktid (PLLA) polimerinden oluşan balonla genişleyebilen scaffold.
- Anit-proliferatif ilaç ve polimer karışımından oluşan scaffold kaplaması:
  - Anti-proliferatif ilaç - Sirolimus (Rapamisin olarak da bilinir)
  - İlaç rezervuarı ve ilaç salım platformu olarak davranan biyouyumlu, biyobozunur (yardımcı madde) Poli-DL-Lactid (PDLLA) polimer kaplaması.
- Altı çift platinum işaretleyici
- Rapid-exchange scaffold taşiyıcı PTCA balon kateter

MeRes100™ Lineage BRS comprises of following components-

- *A balloon-expandable scaffold made from polymer Poly-L-Lactide (PLLA).*
- *A scaffold coating that consists of a blend of anti-proliferative drug and polymer:*
  - *Anti-proliferative drug - Sirolimus (also known as Rapamycin)*
  - *Bio-compatible, bio-degradable polymer (Excipient) Poly-DL-Lactide (PDLLA) coating which acts as drug reservoir and drug release platform.*
- *Six pairs of platinum markers*
- *A rapid-exchange scaffold delivery PTCA balloon catheter*

Katalog Sayıları/*Catalogue Numbers*

Mevcut Scaffold Çapı / *Available Scaffold Diameter* (mm)	**Mevcut Scaffold Uzunluğu / *Available Scaffold Length* (mm)**							
	13	**16**	**19**	**24**	**29**	**32**	**37**	**40**
2.25	MRL22513	MRL22516	MRL22519	MRL22524	MRL22529	MRL22532	MRL22537	MRL22540
2.50	MRL25013	MRL25016	MRL25019	MRL25024	MRL25029	MRL25032	MRL25037	MRL25040
2.75	MRL27513	MRL27516	MRL27519	MRL27524	MRL27529	MRL27532	MRL27537	MRL27540
3.00	MRL30013	MRL30016	MRL30019	MRL30024	MRL30029	MRL30032	MRL30037	MRL30040
3.25	MRL32513	MRL32516	MRL32519	MRL32524	MRL32529	MRL32532	MRL32537	MRL32540
3.50	MRL35013	MRL35016	MRL35019	MRL35024	MRL35029	MRL35032	MRL35037	MRL35040
4.00	MRL40013	MRL40016	MRL40019	MRL40024	MRL40029	MRL40032	MRL40037	MRL40040

Marka *(Trademark):*

MeRes100™ Lineage

Ürünün Tanımı ve İşlevinin Açıklaması
(Identification of the Product and description of its functioning)

MeRes100™ Biyoemilebilir Scaffold sistemi balonla genişleyebilen poli-l-laktid (PLLA) biyoemilebilir vasküler scaffold, scaffoldu kaplayan polimer ve sirolimus karışımı kaplaması, scaffold üzerine yerleştirilmiş 6 çift radyopak platinyum işaretleyici ve rapid exchange PTCA balon kataterinden oluşmaktadır. Scaffold balon katater üzerine oturtulmuş ve iki platinyum-iridyum işaretleyici arasına sabitlenmiştir.
PTCA balon kateter, scaffoldu hedef bölgeye taşıyan ve yerleştiren bir taşıyıcı sistem görevi görür. Balon, salin ile kontrast madde karışımı kullanılarak hidrolik basınç uygulaması ile şişirilir. Monte edilmiş scaffold, balonun şişmesi nedeniyle genişler ve hedef bölgeye yerleşir. Balon söndükten sonra stent genişlemiş halde kalır. Taşıyıcı sistem çıkarılır ve sscaffold, hedef bölgeye kalıcı olarak implante edilir; böylece luminal çapta iyileşme ve kan akışının restorasyonu sağlanmış olur. Bu genişleyebilen biyoemilebilir scaffoldlar daralmış arterleri fiziksel olarak destekler ve iskemik arter hastalığının semptomlarını azaltır. Scaffold zaman içerisinde bozunarak vasküler fizyolojinin restorasyonu sağlanır. Scaffoldun üzerine kaplanmış olan ilaç (yani sirolimus), ikili bir etki mekanizmasına sahiptir. Enflamatuar hücre fonksiyonunu modüle eder ve düz kas hücresi proliferasyonunu bloke eder. Sirolimus ilacı scaffold üzerine, ilaç rezervuarı ile ilaç salım platformu görevi gören, biyobozunur özellikte olan ve iyi bilinen bir polimer kombinasyonu ile birlikte kaplanır. Polimer, ilaç ile neredeyse eşzamanlı olarak salınır ve böylece polimere eğilim minimuma indirilmiş olur.

MeRes100™ Lineage BRS comprises of a balloon expandable bioresorbable PLLA scaffold, a scaffold coating that consists of a blend of sirolimus drug and polymer, six pairs of platinum markers and a rapid exchange Rx balloon dilatation catheter. Scaffold is mounted on a rapid exchange balloon dilatation catheter between two platinum iridium radiopaque markers bands placed on the inner lumen within the balloon segment.
The Rx balloon catheter serves as the scaffold delivery system that delivers and deploys the scaffold to the target site. The balloon is inflated by hydraulic pressurization using mix of saline and contrast medium. The mounted scaffold expands due to inflation of balloon and is deployed to the target site. The scaffold remains expanded after deflation of the balloon. The delivery system is removed and the scaffold is implanted at the target site resulting in improving luminal diameter and restoration of blood flow. These expandable bioresorbable scaffold devices physically support narrowed arteries to alleviate symptoms of ischemic artery disease. The bioresorbable scaffold degrades with time leading to the restoration of vascular physiology. The drug coated on the scaffold i.e. Sirolimus has dual mechanism of action. It modulates inflammatory cell function and blocks smooth muscle cell proliferation. Sirolimus drug is coated on stent with a well-known bio-compatible, bio-degradable polymer coating which acts as drug reservoir and drug release platform. The polymer elutes almost simultaneously as the drug, thus minimizing the propensity for a polymer.

1783-MDD-119, 17.05.2019, Rev.00

AT Tasarım İncelemesine Konu Olan Cihaz Tipi İçin Temin Edilen Teknik Doküman Listesi
(List of the technical documentation provided for the appliance type relating to EC Desing Examination)

Ekli Teknik Doküman Listesi *(List of the technical documentation annexed)*	**Teknik Doküman Referansı** *(Reference of the technical documentation)*
Klinik Değerlendirme Soru Listesi ve Raporu *(Clinical Evaluation Check List and Report)* **1542-MDD-099/2019-01**	***Teknik Dosyasında (In Technical File)***
Tasarım Dosyası Değerlendirme Raporu ***Design Dossier Review Report*** **1542-MDD-099/2019-02**	***Teknik Dosyasında (In Technical File)***
İnceleme Raporu ***(Inspection Report)*** **1542-MDD-099/2018-01**	***Teknik Dosyasında (In Technical File)***

Bu belge ancak TSE- Onaylanmış Kuruluş Numarası 1783 mührü ile geçerlidir.
This certificate is only valid if sealed with "TSE- European Notified Body Number 1783".

1783-MDD-119, 17.05.2019, Rev.00
www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

CERTIFICATE

kiwa

EC Certificate

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

Certificate Number: 1984-MDD-18-479

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

Organization:

BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ

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

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

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

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

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

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

01 March 2019, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

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

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

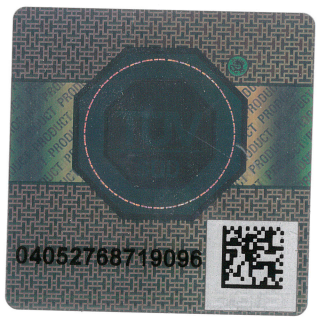
Product Category(ies):

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®

EC CERTIFICATE

Number: 2116857CE01

Full Quality Assurance System

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

Manufacturer:

Biosensors Europe SA

Rue de Lausanne 29
1110 Morges
Switzerland

For the product category(ies)

Drug Eluting Stent System for Coronary Use

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 2116857CN, initially dated 15 July 2008
Addendum, initially dated 15 July 2008

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

This certificate is valid until: 15 July 2022
Issued for the first time: 15 July 2008
Reissued: 17 July 2017
DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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: 2116857CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Drug Eluting Stent System for Coronary Use

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

This certificate covers the following product(s):

BioMatrix Flex™ - Drug Eluting Coronary Stent System

BioMatrix NeoFlex™ - Drug Eluting Coronary Stent System

Initial date: 15 July 2008
Revision date: 17 July 2017

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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: 2116857CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Drug Eluting Stent System for Coronary Use

Issued to:

Biosensors Europe SA
Rue de Lausanne 29
1110 Morges
Switzerland

This certificate covers the following product(s):

LUMENO™ Flex - Drug Eluting Coronary Stent System

Initial date: 6 July 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
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

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 541900**

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

In respect of:

See certificate scope page.

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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Certificate No: CE 541900

Certificate Scope:

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

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

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

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 541900

Issued To:

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

NBOG code(s)	Device description	Intended purpose
Class III		
MD 0102/MD 0106; MDS7006	Angiographic and Guide Catheters	See CE 538238
MD 0102 MDS7006	Drainage Catheters	See CE 541480
MD 0106, MDS7006	Merit Microcatheters	See CE 553250
MD 0106, MDS7006	EN Snare Endovascular Snare System	See CE 555846
MD 0106, MDS7006	InQwire® Diagnostic Guide Wires, InQwire® Amplatz Guide Wires	See CE 560101
MD 0106, MDS7006	Merit Embolectomy Catheters	See CE 561259
MD 0106, MDS7006	Ostial Pro Stent Positioning System	See CE 585005
MD 0106, MDS7006	ONE Snare Endovascular Snare System, ONE Snare Endovascular Microsnare System	See CE 590890
MD 0102, MDS7006	Hemodialysis Catheters	See CE 606106
MD 0106, MDS7006	Merit SureCross™ Support Catheter	See CE 612029
MD 0102, MDS7006	HeRO Graft	See CE 650631
MD 0106, MDS7006	SwiftNINJA Steerable Microcatheters	See CE 667696
MD 0106, MDS7006	True Form Reshapable Guide Wire	See CE 669204

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 541900

Issued To:

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

NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 0200, MDS7006	Biliary Catheter (RBC), Biliary Drainage Cath. (RBDC), CirQ Nephrostomy Catheter	intended for drainage of bile within the biliary system
MD 0200, MDS7006	ReSolve Locking Catheter (RLC)	intended for percutaneous drainage of fluids from body cavities for up to 90 days.
MD 0106, MDS7006	ALIMAXX-ES, EndoMAXX, EndoMAXX EVT	used in the treatment of malignant neoplasms for the purpose of palliating the airway.
MD 0106, MDS7006	AERO Tracheobronchial Stent, AeroMINI, AERO Delivery System	indicatedfor the use in the treatment of tracheobronchial strictures and airway compressions (stenosis) produced by malignant neoplasms
MD 0106, MDS7006	Biliary Stents & Delivery System: ALIMAXX-B	indicated for the palliation of malignant strictures in the biliary tree
MD 1104, MDS7006	Bipolar Coagulation Probe and related accessories	Probes function as conventional electro-coagulation devices when supplied withcurrent from a standard bipolar electro-surgical generator. The probes are intended to provide hemostasis throughout the gastrointestinal tract.
MD 0102, MDS7006	Flex-Neck® Classic, Infant, ARC, ExxTend Catheters	intended for implantation for more than 30 days to carry fluid into and out of the abdomen

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 541900

Issued To:

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

NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 0106, MDS7006	Peritoneal Dialysis Catheter Embedding Tool	indicated for embedding the external portion of most PD catheters subcutaneously in anticipation of future retrieval of the part of the catheter
MD 0202, MDS7006	StabiliT ER2 Bone Cement and Saturate Mixing System	intended for use in treatment of pathological fractures of the vertebrae using vertebroplasty or kyphoplasty procedure
MD 1402, MDS7006	SpineSTAR Tumor Ablation Systems (instruments and kits)	intended for the ablation of tumor within the vertebral body. It heats targeted tissue in contact with the electrode
MD 1402 (non-sterile)	MetaSTAR RF Generator	intended to generate and control the delivery of RF energy for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body
MD 0200, MDS7006	BioSphere Bearing nsPVA	used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs)
MD 0202, MDS7006	StabiliT Vertebral Augmentation & Vertebroplasty Kits (Class IIb kits under article 12)	for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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bsi.

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 541900

Issued To:

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

NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 0202, MDS7006	StabiliT Vertebral Augmentation & Vertebroplasty Kits (Class IIb kits under article 11)	for the treatment of pathological fractures of the vertebrae using a vertebroplasty or kyphoplasty procedure
Class IIa		
MD 0102, MDS7006	Fountain & Mistique Infusion Catheters	NA for class IIa devices
MD 0102, MDS7006	One Step Centesis Drainage Catheter	NA for class IIa devices
MD 0102, MDS7006	ReSolve Non-Locking Catheter (RNL), Resolve Dilator	NA for class IIa devices
MD 0104, MDS7006	Intelliflator & Merit Monitor (IntelliSystem), DiamondTOUCH, Monarch, Blue Diamond, Endotek Digital Inflation Syringes	NA for class IIa devices
MD 0106, MDS7006	Introducer, Mini Access, Radial, Plastic Jacket Guide Wires	NA for class IIa devices
MD 0106, MDS7006	MAXXWIRE & ENDOWIRE (Aero) Guide Wires	NA for class IIa devices
MD 0106, MDS7006	Manifolds, Stopcocks, Rotating Adapters, Flow Switch, TRAM	NA for class IIa devices
MD 0106, MDS7006	MAK/SMAK, MAK-NV, Vessel Dilator	NA for class IIa devices
MD 0106, MDS7006	Valve Adapter	NA for class IIa devices
MD 0102, MDS7006	High Pressure Contract Injection and Pressure Monitoring Tubing	NA for class IIa devices
MD 0104, MDS7006	MeriTrans™ and Argotrans Disposable Transducers	NA for class IIa devices

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 541900

Issued To:

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

IIa

NBOG code(s)	Device description	Intended purpose
Class ~~IIb~~		
MD 0106, MDS7006	Merit Angioplasty Pack (MAP Kits)	NA for class IIa devices
MD 0106, MDS7006	FLO50, PhD, Passage, Access-9, AccessPLUS, DoublePlay, MBA, MBA Plus, Honor, FLO30, FLO40, FLO40XR Hemostasis Valves	NA for class IIa devices
MD 0106, MDS7006	Prelude (PSI & PRO), HVA, PreludeEASE, Prelude short Sheath, Dilator & Obturator	NA for class IIa devices
MD 0106, MDS7006	Advance™ Merit Angiographic Needles	NA for class IIa devices
MD 0106, MDS7006	Futura™ Safety Scalpel	NA for class IIa devices
MD 0106, MDS7006	OuTake Catheter Extractor Device	NA for class IIa devices
MD 0102, MDS7006	Contrast Management Systems (high pressure use)	NA for class IIa devices
MD 0102, MDS7006	CT Transfer Set - FAS	NA for class IIa devices
MD 0106, MDS7006	Flow Guard™ Valved Peelable Introducer	NA for class IIa devices
MD 0106, MDS7006	Hart Chiba & Trocar Style Needles	NA for class IIa devices
MD 0106, MDS7006	Merit Advance Angiographic Safety Needles	NA for class IIa devices
MD 0106, MDS7006	Laureate Guide Wire (peripheral and urological)	NA for class IIa devices
MD 0106, MDS7006	Peritoneal Dialysis Implantation Kits	NA for class IIa devices
MD 0106, MDS7006	Corvocet Coaxial Introducer and Biopsy System	NA for class IIa devices
MD 0106, MDS7006	HeRO Accessory Kit	NA for class IIa devices
MD 0106, MDS7006	Hydraulic Assembly and Hydraulic Master Syringe Assembly	NA for class IIa devices
MD 1402, MDS7006	Activation Element	NA for class IIa devices

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IIa

NBOG code(s)	Device description	Intended purpose
Class IIb		
MD 1402 (non-sterile)	Multiplex Controllers	NA for class IIa devices
MD 0103, MDS7006	StabiliT and STAR Instruments	NA for class IIa devices
MD 0106, MDS7006	Advocate PTA Balloon Catheter	NA for class IIa devices
MD 0108, MDS7006	DualCap System	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Access Cannulas and Stylets	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Steerable Needles	NA for class IIa devices
MD 0106, MDS7006	Bone Filler Devices	NA for class IIa devices
MD 0106, MDS7006	Bone Drills	NA for class IIa devices
MD 0106, MDS7006	Pursue (Hi-Lex) Microcatheter	NA for class IIa devices
MD 0106, MDS7006	Osseoflex Cement Delivery System	NA for class IIa devices
MD 0106, MDS7006	Bone Marrow Aspiration Needle	NA for class IIa devices
Class Is		
MDS7006	Squirt Fluid Dispensing System	NA for class Is devices
MDS7006	External Vascular Compressors / RadStat Radial Artery Compression System; Compression Discs	NA for class Is devices
MDS7006	Tags / PAL Pen and Labels; Custom PAL Labels; PAL Pen	NA for class Is devices

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NBOG code(s)	Device description	Intended purpose
Class Is		
MDS7006	Basins / Backstop® Disposal Basin; Ministop Disposal Basins; BackStopPlus Disposal Basis; MiniStopPlus Disposal Basin; Triple Play™ Disposal Basin; Dugout® DisposalBasin; RingMaster Guide Wire Basin	NA for class Is devices
MDS7006	Valves / Check Relief Valve; In - Line Check Relief Valve [CRV] Caotiva® Blood Containment Device	NA for class Is devices
MDS7006	Catheter Tubeholders / Revolution Catheter Securement Device	NA for class Is devices
MDS7006	Fluid Administration Set; Fluid Administration Spike; Fluid Management Tube	NA for class Is devices
MDS7006	Merit Miser Contrast Management System	NA for class Is devices
MDS7006	Continuous Flush Devices	NA for class Is devices
MDS7006	Merit Angioplasty Packs	NA for class Is devices
MDS7006	Waste Disposal System	NA for class Is devices
MDS7006	Merit Disposal Depot	NA for class Is devices
MDS7006	Shortstop and Shortstop Advantage Temporary Sharps Holders	NA for class Is devices
MDS7006	Procedure Packs (Custom Kits); Rapid Response Kits	NA for class Is devices
MDS7006	Connection Tubes	NA for class Is devices
MDS7006	Syringes	NA for class Is devices

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NBOG code(s)	Device description	Intended purpose
Class Is		
MDS7006	Syringes	NA for class Is devices
MDS7006	Merit Drainage Depot	NA for class Is devices
MDS7006	Basix™ Inflation Syringe; BasixCOMPAK Inflation Syringe; BasixTOUCH Inflation Syringe	NA for class Is devices
MDS7006	Angiography and Angioplasty Procedures Accessories of Class I Sterile / RXP® Rapid Exchange Prep Syringe; Guide Wire Insertion Tool; Pin Vice Torque Device; H20 TORQ Device; SeaDragon Torque Device	NA for class Is devices
Class Im		
MD 1301 (non-sterile)	Monitors / IntelliSystem® II Color Monitor	NA for class Im devices
MD 0104 (non-sterile)	AeroSIZER Stent Measuring System	NA for class Im devices

First Issued: **2008-10-03** Date: **2019-02-08** Expiry Date: **2023-10-02**

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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

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ADDENDUM

Belonging to certificate: 3812454CE01

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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
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ADDENDUM

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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

Bentley

MANUFACTURER'S DECLARATION OF CONFORMITY

According to the EC – Medical Devices Directive 93/42/EEC, as last amended by Directive 2007/47/EC

FULL QUALITY ASSURANCE PROCEDURE

DECLARATION DE CONFORMITÉ DU FABRICANT
selon la Directive CE 93/42/CEE relative aux dispositifs médicaux modifiée par la directive 2007/47/CE
SYSTÈME COMPLET D'ASSURANCE QUALITÉ

	Reference: *Référence:*	**DoC**	**18-004**
Manufacturer's Name & Business Address : *Nom du fabricant et adresse postale:*		**Bentley InnoMed GmbH Lotzenäcker 25, 72379 Hechingen, Germany**	
Manufacturing Location: *Adresse de la production:*		**Lotzenäcker 3, 72379 Hechingen, Germany**	
Medical Device Trade Name: *Dénomination commercial du dispositif médical:*		**BeGraft Coronary Stent Graft System**	
Medical Device Generic Name: *Dénomination générique du dispositif médical:*		**Coronary Stent Graft System** ***Système d'endoprothèse coronaire couverte***	
Classification: *Classification:*	Class: *Classe:*	**III**	acc. Annex IX MDD 93/42/EEC, rule: *selon annexe IX DDM 93/42/CEE, règle :* ***8***
GMDN Code : *Code GMDN:*	***57788***	Term: *Terme:*	***Mesh-sleeve coronary artery stent***
UMDNS Code: *Code UMDNS:*	***17-461***	Term: *Terme:*	***Stent, Vascular***

This declaration is applicable to below listed models/variants (REFs):
La présente déclaration s'applique à tous les lots de références mentionnées ci-dessous :

Stent Diameter / *diamètre stent* [mm]	Stent Length / Longueur stent [mm]					
	8	12	16	18	21	24
2.50	BG08250	BG12250	BG16250	BG18250	BG21250	BG24250
2.75	BG08275	BG12275	BG16275	BG18275	BG21275	BG24275
3.00	BG08300	BG12300	BG16300	BG18300	BG21300	BG24300
3.50	BG08350	BG12350	BG16350	BG18350	BG21350	BG24350
4.00	BG08400	BG12400	BG16400	BG18400	BG21400	BG24400
4.50	n.a.	n.a.	BG16450	BG18450	BG21450	BG24450
5.00	n.a.	n.a.	BG16500	BG18500	BG21500	BG24500

Herewith we declare, under our sole responsibility, that each lot of above mentioned medical device, to which the Full Quality Assurance Procedures have been applied, complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Bentley

Nous déclarons sous notre entière responsabilité que chaque lot des dispositifs médicaux mentionnes ci-dessus, auxquels le système complet d'assurance qualité a été appliqué, correspond aux exigences essentielles, aux règles de classification, applicables a toutes les phases, depuis la conception du dispositif jusqu'à 'a son contrôle final avant livraison.

Conformity Assessment Body (acc. MDD 93/42/EEC, Annex XI) *Organisme notifié (selon annexe XI DDM 93/42/CEE)*	Notified Body Number *No de l'Organisme notifié*	Address *Adresse*
MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH	*0482*	*Pilatuspool 2, 20355 Hamburg, Germany*

Certificate Type *Type de certificat*	Certificate Number *No certificat*	Assessment route acc. MDD 93/42/EEC *Procédures d'évaluation de conformité, selon DDM 93/42/CEE*
Full Quality Management System (class I(s), I(m), IIa, IIb, III) *Certificat du Système complet d'assurance qualité (classe I(s), I(m), IIa, IIb, III)*	*7490GB410180410*	*Annex II, excluding section 4* *Annexe II, à l'exclusion de section 4*
Design Examination Certificate (class III devices only) *Certificat d'examen CE de la conception (que pour dispositifs de classe III)*	*13850GB411180410*	*Annex II, section 4* *Annexe II, section 4*

This Declaration is valid until:
La présente déclaration est valable jusqu'au : *June 24th, 2022*

Authorized Signatory:
Signataires autorisés:

Frank Schulte-Hunsbeck — *April 12th, 2018*
Manager Quality Assurance / Regulatory Affairs — Date

Milisav Obradovic — *April 12th, 2018*
Site Manager and Technical Director — Date