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<br>000-299 Standard (subassembly) design<br>300-599 Design variation 1<br>600-899 Design variation 2<br>900-999 Design variation 3 / Overflow | Odd numbers contain a side hole<br>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.<br>For example,<br>E – Econopack<br>L – Long Bright Tip<br>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.<br>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<br>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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# 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**<br>**3200 Lakeside Drive**<br>**Santa Clara**<br>**California**<br>**95054**<br>**USA** |

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

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

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

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|---|---|
| Certificate No: | **CE 510108** |
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| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Abbott West Distribution Center<br>42301 Zevo Drive<br>Temecula<br>California<br>92590<br>USA | **Distribution**<br>**Manufacture** |
| Acme Monaco<br>75 Winchell Drive<br>New Britain<br>CT 06052<br>USA | **Manufacture** |
| Ad)medes Schuessler GmbH<br>Rastatter Strasse 15<br>75179 Pforzheim<br>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

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

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Availmed S.A. de C.V.<br>C. Industrial Lt. 001 Mz.105<br>No. 20905 Int. A<br>Col. Cd. Industrial<br>Tijuana<br>Baja California<br>22444<br>Mexico | **Manufacture** |
| Nitinol Devices and Components, Inc.<br>Costa Rica, S.R.L<br>Coyol Free Zone<br>Building B14 and B15<br>El Coyol, Alajuela<br>Costa Rica | **Manufacture** |
| Nitinol Devices and Components, Inc<br>47533 Westinghouse Drive<br>Fremont<br>CA 94539<br>USA | **Manufacture** |

# EC Certificate - Full Quality Assurance System

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

# List of Significant Subcontractors

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

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Novartis Pharma AG<br>Lichtstrasse 35<br>Basel<br>CH-4056<br>Switzerland | **Crucial Supplier** |
| Parter Sterilization Services LLC<br>17115 Kingsview Ave<br>Carson<br>CA 90746<br>USA | **ETO Sterilization** |
| Rose Technologies<br>1440 Front Avenue NW<br>Grand Rapids<br>Michigan 49504<br>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

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

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Sterigenics Costa Rica S.R.L.<br>Zona Franca PROPARK<br>Calle Principal, Edificio 10<br>El Coyol<br>Alajuela<br>Costa Rica | **ETO Sterilization** |
| Sterigenics Germany GmbH<br>Kasteler Strasse 45<br>65203 Wiesbaden<br>Germany | **ETO Sterilization** |
| Sterigenics UK Limited<br>Cotes Park Estate<br>Somercotes<br>Alfreton DE55 4NJ<br>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**<br>**3200 Lakeside Drive**<br>**Santa Clara**<br>**California**<br>**95054**<br>**USA** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Sterigenics US, LLC<br>2400 Airport Road<br>Santa Teresa<br>New Mexico<br>88008<br>USA | **ETO Sterilization** |
| Sterigenics US, LLC<br>4900 South Gifford Avenue<br>Los Angeles<br>CA 90058<br>USA | **ETO Sterilization** |
| Sterigenics US, LLC<br>7695 Formula Place<br>San Diego<br>California<br>92121<br>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:

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

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| Synergy Health AST, SRL<br>B16, Street 4, Avenue 0<br>El Coyol Free Zone<br>20102 El Coyol<br>Alajuela<br>Costa Rica | **E beam Sterilization** |
| Synergy Health Ireland Ltd.<br>IDA Business & Technology Park<br>Sragh Industrial Estate<br>Tullamore, Co. Offaly<br>Ireland | **E beam Sterilization**<br>**ETO Sterilization** |
| Teleflex Medical OEM<br>50 Plantation Drive<br>Jaffrey<br>NH 03452<br>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.<br>Remove Business Unit name (Cardiac Therapies) from the 'issued to' address and the Abbott Vascular, Murrieta facility address in the list of subcontractors.<br>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<br>Removal of Sterigenics (Salt Lake City), Abbott Ireland (Galway) and Isotron Ireland as significant subcontractors. Remove Abbott Vascular Sterilization from Clonmel manufacturing site.<br>Addition of Sterigenics (New Mexico) as significant subcontractor.<br>Removal of atherctomy catheters and motor drive units from the scope. Redefine stents as stent systems.<br>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.<br>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. |

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# 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2008-10-03** Date: **2019-05-09** Expiry Date: **2023-10-02**

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By Royal Charter

Certificate No: CE 541900

# Certificate Scope:

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

**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: **2019-05-09** 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 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: **2019-05-09** 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 | indicated for 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 with current 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 |
| MD1104, MDS7006 | ClariVein Infusion Catheter | indicated for infusion of physician-specified agents in the peripheral vasculature including for endovascular occlusion of incompetent veins in patients with superficial venous reflux. |

First Issued: **2008-10-03** Date: **2019-05-09** 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: **2019-05-09** Expiry Date: **2023-10-02**

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**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 |

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|---|---|---|
| **Class IIa** | | |
| 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 | Guide Wires | 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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| **Class IIa** | | |
| 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 | Merit Microcatheters | 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 |
| MD 0102, MDS7006 | Angiographic Peripheral Catheters | 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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|---|---|---|
| **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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| **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 |

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