Supreme™ Diagnostic Connecting Cables

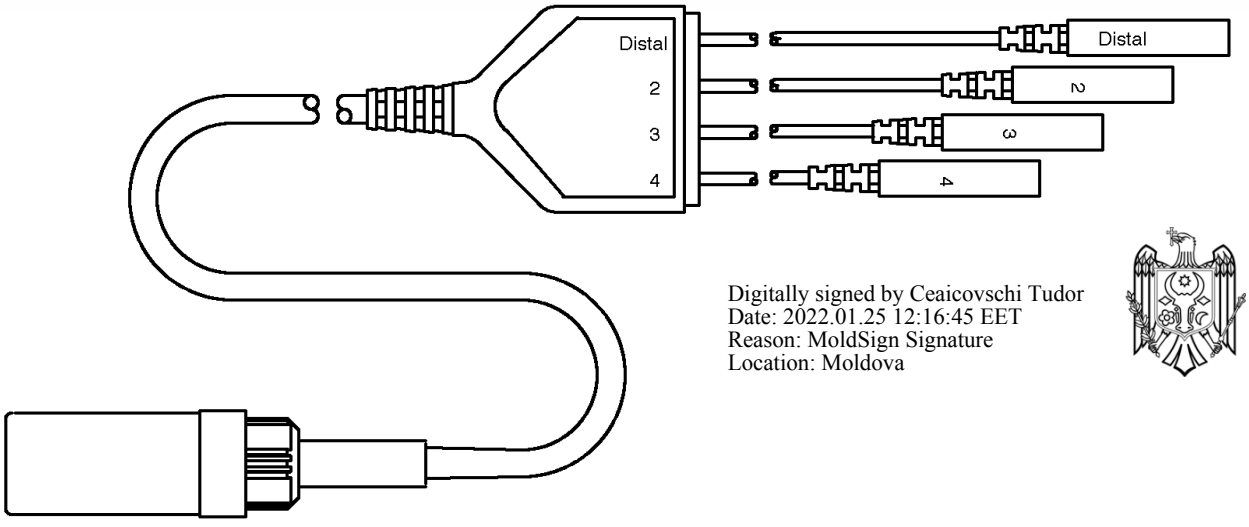
Product Highlights

- Colored cables available for easy identification during multiple-catheter procedures
- Guided channel for fast, convenient connection
- Clearly labeled terminal pins
- 24K gold-plated pins
- Shrouded 2 mm pin connector leads

Ordering Information

Extension cable (1 unit per box)

Reorder Number	Color	Connects these Supreme™ Catheters	Usable Length (cm)
401980	Black	Bipolar and Quadripolar	150
401981	Blue	Bipolar and Quadripolar	150
401982	Grey	Bipolar and Quadripolar	150
401983	Red	Bipolar and Quadripolar	150
401984	Black	Hexapolar	150
401985	Black	Octapolar and Decapolar	150
401986	Black	Octapolar and Decapolar	210



Digitally signed by Ceaicovschi Tudor
Date: 2022.01.25 12:16:45 EET
Reason: MoldSign Signature
Location: Moldova

EC Certificate - Full Quality Assurance System

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

No. **CE 548213**

Issued To: **St. Jude Medical**
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

In respect of:

The Design and Manufacture of Electrophysiology (EP) Catheters, Pacing Catheters, Cardiac Ablation Catheters, Transseptal Needles, and Introducers.
Those aspects of Annex II related to securing and maintaining sterility in the manufacture of cables/leads for use with Electrophysiology Catheters.

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: **2009-07-01** Date: **2020-10-09** Expiry Date: **2024-05-26**

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Supplementary Information to CE 548213

Issued To:

St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

Number	Device Name	Intended purpose per IFU
Class III		
---	Livewire TC™ Ablation Catheter	See CE 548274
---	Livewire™ Electrophysiology Catheter	See CE 548275
---	Supreme™ Electrophysiology Catheter	See CE 548277
---	Response™ Electrophysiology Catheter	See CE 548278
---	Response™ Electrophysiology Catheter with Lumen	See CE 548279
---	Reflexion Spiral™ and Reflexion HD™ Electrophysiology Catheters	See CE 551160
---	BRK™ Transseptal Needle	See CE 553178
---	Safire™ Bidirectional Ablation Catheter	See CE 553725
---	Livewire™ Diagnostic Catheter, MediGuide Enabled™	See CE 562920
---	Agilis EPI Steerable Introducer	See CE 566714
---	Pacel™ Bipolar and Pacel™ Flow Directed Pacing Catheters	See CE 569561
---	Agilis NxT Steerable Introducers	See CE 571321
---	Therapy ComfortGrip™ Bi-Directional Ablation Catheter	See CE 675092
Class Is		
MD 0106	Electrophysiology catheter cables	---

First Issued: **2009-07-01** Date: **2020-10-09** Expiry Date: **2024-05-26**

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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 548213**
Date:	**2020-10-09**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
Abbott Vascular Netherlands B.V. Argonstraat 1 6422 PH Heerlen The Netherlands	**Labelling** **Packaging**
Isomedix Operations, Inc. 380 90th Avenue NW Minneapolis Minnesota 55433 USA	**ETO Sterilization**
Isomedix Operations, Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**

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

List of Significant Subcontractors

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Date:	**2020-10-09**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
Midwest Sterilization Corporation 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**
St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture**
St. Jude Medical 2305 Walnut Street Roseville Minnesota 55113 USA	**Labelling** **Packaging**

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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 548213**
Date:	**2020-10-09**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 Zaventem 1935 Belgium	**EU Representative** **Labelling** **Packaging**
St. Jude Medical Costa Rica Ltda. Edificio #44, Calle 0, Ave. 2 Zona Franca El Coyol, Alajuela Costa Rica	**Manufacture**
Sterigenics US, LLC 5725 W. Harold Gatty Dr. Salt Lake City Utah 84116 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 548213**
Date:	**2020-10-09**
Issued To:	**St. Jude Medical** **14901 DeVeau Place** **Minnetonka** **Minnesota** **55345-2126** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health AST SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone 20102 El Coyol Alajuela Costa Rica	**ETO Sterilization**
UNIMED S.A. Rue du Grand-Pré 10 1007 Lausanne Switzerland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 548213**

Date: **2020-10-09**

Issued To: **St. Jude Medical**
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Date	Reference Number	Action
01 July 2009	7339810	First issue – Transfer from another Notified Body (Phase 1 and 2)
01 October 2009	7441035	Transseptal Access System, Transseptal Needles and Occlusion Catheters added to scope – Transfer from another Notified Body (Phase 3)
26 November 2010	7607541	Add Guidewires to the scope
07 March 2011	7648853	Certificate Renewal Addition of MicroGroup as a significant subcontractor
31 May 2012	7833380	Addition of significant subcontractors HEI, Inc. and Merit Medical Systems, Inc.
18 February 2013	7691361	Addition of Kendall as a significant subcontractor
15 October 2013	8026882	Addition of St. Jude Medical Plymouth as a significant subcontractor for manufacture
30 October 2014	8239559	Addition of St. Jude Medical, Costa Rica Ltda. as a significant subcontractor for manufacturing and Synergy Health AST, SRL in Costa Rica as a significant subcontractor for sterilization.
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 548213**

Date: **2020-10-09**

Issued To: **St. Jude Medical**
14901 DeVeau Place
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Date	Reference Number	Action
23 February 2016	8455226	Certificate renewal. Change the name of Kendall to Covidien LLC. Change the name of MicroGroup to Chandler Industries.
17 June 2016	8557130	Addition of Sterigenics Willowbrook, IL as a sterilizer.
09 December 2016	8632748	Removal of subcontractors Chandler Industries and Covidien LLC. Correction of UNIMED S.A. address.
07 November 2018	9644059	Addition of Pacing Catheters to scope.
05 March 2019	7780627	Traceable to NB 0086.
15 April 2019	9751662	Addition of Sterigenics US, LLC, Salt Lake City, Utah USA as significant subcontractor for ETO Sterilization.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
04 October 2019	9768238	Certificate Renewal. Addition of product table. Removal of Occlusion Catheters, Transseptal Access System, Guidewires, and Related Accessories from scope. Addition to scope of sterility aspects of cables/leads for use with electrophysiology catheters. Removal of subcontractors Lake Region Medical (Chaska, Minnesota), Lake Region Medical Limited (New Ross, Ireland), and Merit Medical Systems, Inc. Addition of subcontractors Isomedix Operations, Inc. (Temecula, California), Midwest Sterilization Corporation (Jackson, Missouri) for ETO Sterilization and St. Jude Medical (Roseville, Minnesota) for Packaging and Labelling. Minor changes to formatting of additional subcontractor names and addresses.
07 August 2020	3158727	Removal of subcontractor 'Sterigenics (Willowbrook, IL)'
Current	3297537	Sterilization change from BIs to parametric release. Change affecting all ETO sterilized products covered by this certificate. Addition of significant subcontractor Abbott Vascular Netherlands B.V. for the activities of labelling and packaging.

SJM Declaration of Conformity for Minnetonka Catheter Connecting Cables

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC as amended by 2007/47/EC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:
St. Jude Medical
14901 DeVeau Place
Minnetonka, Minnesota 55345-2126, USA

European Representative:
St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:
Cable Accessories

Product Name(s)/ Model Number(s):

Product Name	Model/Reorder Number
Livewire TC™ Catheter Extension Cable	402505, 402543, 402544
Response™ Electrophysiology Extension Cable	401661, 401970, 401971, 401972, 401973, 401974, 401975, 401976, 401977
Supreme™ Electrophysiology Extension Cable	401980, 401981, 401982, 401983, 401984, 401985, 401986
Safire™ Catheter Extension Cable	402558, 402560, 402561, 402566, 402567
Therapy ComfortGrip™ Extension Cable	A-TCG-402558, A-TCG-402560, A-TCG-402561, A-TCG-402566, A-TCG-402567

Classification:
Class I sterile, Rule 1 according to Annex IX of the MDD 93/42/EEC

GMDN Code(s):
47487

Original CE Mark Date:
01-Jul-2009

Certificate No and expiration date:
Certificate No: CE 548213
Expiration Date: 26-May-2024

Applicable Quality System Standards:
EN ISO 13485:2016

Notified Body:
BSI Group The Netherlands B.V.
Say Building
John M. Kaynesplein 9
1066 EP Amsterdam
The Netherlands

Signature:

Blair Schwartz
Regulatory Manager

09 Mar 2020
Issue Date: March 9, 2020

SJM Declaration of Conformity for Minnetonka Catheter Connecting Cables

Notified Body Number: 2797 (Traceable NB number 0086, BSI Reference 7780627)

Signature:

Blair Schwartz
Regulatory Manager

09 Mar 2020
Issue Date: March 9, 2020