Catheter Connection Cables for Therapy,™ Safire™ BLU™ Duo and Contact Enabled™ Ablation Catheters

Product Highlights

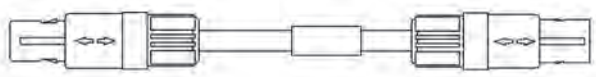
- Compatible cables for Therapy™ and Safire™ BLU™ Duo catheters to compatible generators

Ordering Information

Reorder Number	Model Number	Length (cm)	Catheter	Generator
85641	1641	250	Therapy™ Series Single Thermocouple/Therapy™ Dual-8™/ Therapy™ Cool Path™/ Therapy™ Cool Path™ Duo/ Therapy™ Cool Flex™/ Safire™ BLU™ Duo	IBI-1500T Series
85644	1641-A	250	Therapy™ Series Single Thermocouple/Therapy™ Dual-8™/ Therapy™ Cool Path™/ Therapy™ Cool Path™ Duo/ Therapy™ Cool Flex™/ Safire™ BLU™ Duo	IBI-1500T Series
85708	1711-MA	250	Therapy™ Series Thermocouple	Medtronic Atakr
85709	1713-WA	250	Therapy™ Series Thermocouple	Stockert Shuttle
85711	1711-M	250	Therapy™ Series Thermocouple	Medtronic Atakr
85713	1713-W	250	Therapy™ Series, Single Thermocouple	Stockert Shuttle
85739	1739-W	250	Therapy™ Dual-8™	Stockert Shuttle
85761	1761-W	250	Therapy™ Series Thermistor; 4 mm tip	Stockert Shuffle
85763	1763-E	250	Therapy™ Series Thermistor; 4 mm tip	EPT-1000 XP
85765	1763-EA	250	Therapy™ Series Thermistor; 4 mm tip	EPT-1000 XP
A402892	1611	250	Contact Enabled™	IBI-1500T Series

1711-M 1711-MA

1641, 1641-A, 1713-W, 1713-WA, 1739-W, 1761-W, 1763-E, 1763-EA



1611

ST. JUDE MEDICAL

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 85222**

Issued To: **Irvine Biomedical, Inc.**
a St. Jude Medical Company
2375 Morse Avenue
Irvine
California
92614
USA

In respect of:

Those aspects of Annex V related to the sterility of electrophysiology cables

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2004-07-09** Date: **2019-07-08** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 85222

Issued To:

Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Avenue
Irvine
California
92614
USA

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Sterile electrophysiology cables	---

First Issued: **2004-07-09** Date: **2019-07-08** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 85222**
Date:	**2019-07-08**
Issued To:	**Irvine Biomedical, Inc.** **a St. Jude Medical Company** **2375 Morse Avenue** **Irvine** **California** **92614** **USA**

Subcontractor:	**Service(s) supplied**
Parter Sterilization Services 17115 Kingsview Avenue Carson California 90746 USA	**ETO Sterilization**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventern Belgium	**EU Representative** **Labelling** **Packaging**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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bsi.

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 85222**

Date: **2019-07-08**

Issued To: **Irvine Biomedical, Inc.**
a St. Jude Medical Company
2375 Morse Avenue
Irvine
California
92614
USA

Date	Reference Number	Action
09 July 2004		First Issued
12 February 2007		Name changed to include "a St. Jude Medical Company"
06 July 2009	7387963	Certificate renewal Addition of EU Representative and amendment to company name for Parter Medical Products.
10 June 2014	8152130	Certificate renewal. Removed NamSA as a critical subcontractor.
05 March 2019	7781598	Traceable to NB 0086.
Current	9969791	Certificate Renewal. Addition of product table. Removal of Irvine Biomedical, 2382 Morse Avenue, as significant subcontractor. Correction to subcontractor addresses. Addition of "Packaging" and "Labeling" activities to St. Jude Coordination Center BVBA.

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ST. JUDE MEDICAL

SJM Declaration of Conformity Electrophysiology Cables

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex V 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:

Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Ave
Irvine, CA 92614, 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):

Electrophysiology Cables

Model Number(s):

Cable Model	Reorder Number
1641	IBI-85641
1689	IBI-85643
1641-A	IBI-85644
1684-TH	IBI-85684
1711-MA	IBI-85708
1713-WA	IBI-85709
1711-M	IBI-85711
1713-W	IBI-85713
1719-W	IBI-85719
1735-D	IBI-85735
1739-W	IBI-85739
1760-M	IBI-85760
1761-W	IBI-85761
1762-W	IBI-85762
1763-E	IBI-85763
1764-W	IBI-85764
1763-EA	IBI-85765
1769-BS	IBI-85769
1611	A402892
1804-S	IBI-85809
1910-S	IBI-85930
1924-S	IBI-85931
1910-S	IBI-85942

Signature:

08 Jul 2019
Issue Date

Legal Manufacturer
Adam Ettl
Regulatory Affairs Manager

ST. JUDE MEDICAL

SJM Declaration of Conformity Electrophysiology Cables

1914-SA	IBI-85945
1904-SA	IBI-85953
1910-SA	IBI-85954
1914-SA	IBI-85955
1924-S8	IBI-89002
2101-C	IBI-85201
2102-C	IBI-85205

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

GMDN Code(s): 46429

Original CE Mark Date: 09 July 2004

Certificate No and expiration date: Certificate No: CE 85222
Expiration Date: 26 May 2024

Applicable Quality System Standards: ISO 13485:2016

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

Notified Body Number: 2797 (Traceable to NB number 0086, BSI Reference 7781598)

Manufacturing Facilities: Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Ave
Irvine, CA 92614, USA

Signature: _____ 08 Jul 2019

Legal Manufacturer
Adam Ettl
Regulatory Affairs Manager

Issue Date

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Medical Costa Rica Ltda.
Edificio #44
Calle 0, Ave. 2
Zona Franca Coyol
El Coyol, Alajuela
Costa Rica

Holds Certificate No: **FM 728657**

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

Manufacture and distribution of radio-frequency (RF) ablation catheters, electrophysiology (EP) catheters, intracardiac echocardiography catheters, cardiac mapping system accessories, transseptal access system, introducer catheters, vascular closure systems; and the design of cardiac mapping system accessories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-06
Effective Date: 2021-12-14
Latest Revision Date: 2022-03-22
Expiry Date: 2024-12-13

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CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

has implemented and maintains a **Quality Management System**.

Scope:
Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	497269 QM15
Valid from	2021-06-16
Valid until	2024-06-15
Date of certification	2021-06-16

DQS GmbH

Markus Bleher
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Romania, Str. Bucatului nr. 11, 020565 Bucharest - Romania

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

Str. Mantuleasa nr. 33, Sector 2
023961 Bucuresti
Romania

Location	Scope
075906 **Sante International SA** **Sos. Mihai Bravu nr. 7, bl. P37-P37A, sector 2** **021303 Bucuresti** **Romania**	Import, trade and storage of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices. Consulting for state and private medical units.
497270 **Sante International SA** **Str. Pupitrului, nr. 81, sect. 3** **033036 Bucuresti** **Romania**	Storage of medical and laboratory equipment, disinfectants, laboratory reagents,cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050285 **Sante International SA** **Calea Ghirodei, nr. 36** **300327 Timisoara** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050284 **Sante International SA** **Calea Dorobantilor, nr. 111** **400609 Cluj-Napoca** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.
31050283 **Sante International SA** **Str. Lascar Catargi, nr. 37** **700107 Iasi** **Romania**	Trade of medical and laboratory equipment, disinfectants, laboratory reagents, cardiovascular surgery devices, service for medical and laboratory equipment. Consulting for state and private medical units.

This annex (edition:2021-06-16) is only valid in connection with the above-mentioned certificate.