Cool Point Irrigation Pump

Engineered for Control, Safety, and Ease of Use

Control

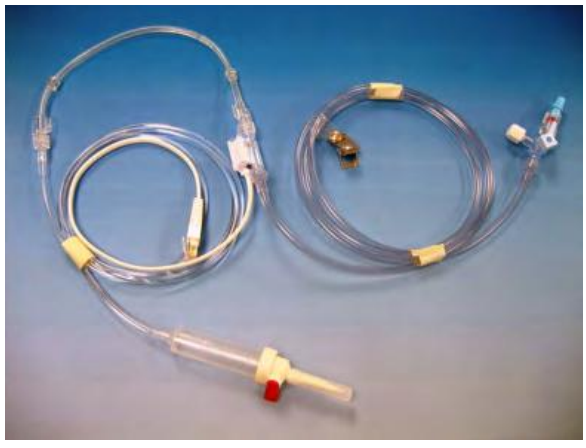
- Direct communication with IBI-1500T11 cardiac ablation generator
- Fully programmable flow rates – up to 40 ml/min*
- Tracks and displays total irrigation volume

Safety

- Exclusive in-line occlusion detection
- Dual bubble detectors:
  - 2 µL air bubble detection
  - Bubble detection diagnostic self-check

Ease of Use

- Plug-and-play use with IBI-1500T11 cardiac ablation generator
- Flow rate displayed on highly visible LED
- Compact size, lightweight design – can be mounted on an IV pole



Cool Point Tubing Set specially designed for easy connection. An in-line occlusion sensor helps ensure safe operation.

Specifications

Mechanism:	Peristaltic
Dimensions:	29 cm x 21 cm (including handle) x 18.5 cm (including pump head) (W x H x D)
Weight:	3.75 kg
Flow Rates:	Low flow: 1 to 5 ml/min (1 ml/min increments)
	High flow: 6 to 40 ml/min (1 ml/min increments)
Priming Flow Rate:	60 ml/min
Air Bubble Detection:	2 µL
Alarms:	Bubble detection; communication lost; door open; pressure sensor not connected; occlusion

Ordering Information

Item Number	Description
85784	Cool Point Irrigation Pump
85786 (Model Number 1779)	Communication cable for the Cool Point Irrigation Pump
85785	Cool Point tubing set (sold individually)

*When the Cool Point irrigation pump is used with Therapy Cool Path irrigated ablation catheters, a maximum flow rate of 17 ml/min is recommended.

Visit our website: sjm.com/irrigatedsystem
For further information, please call:

Product manufactured by Irvine Biomedical, Inc., a St. Jude Medical Company.

Information contained herein for distribution outside of the US only.

ST. JUDE MEDICAL

CE 0086

St. Jude Medical, Inc.
Global Headquarters
One Lillehei Plaza
St. Paul, MN 55117
651 483 2000
Telex: 298453
651 766 3045 Fax

St. Jude Medical Europe sprl
The Corporate Village
Avenue Leonardo Da Vinci laan 15
B-1935 - Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brazil Ltda.
Rua Frei Caneca, 1380-9 A-CJ91/92
Sao Paulo - SP - Brasil
CEP 01307-002
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Unit 2701-07, COSCO Tower,
Grand Millennium Plaza
183 Queen's Road,
Central, Hong Kong
+852 2996 7688
+852 2956 0622 Fax

GMAF163

EC Certificate - Full Quality Assurance System

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

No. **CE 58528**

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

In respect of:

The design, development and manufacture of electrophysiology and radiofrequency ablation catheters, intracardiac catheters used for echocardiography, irrigation pumps, irrigation tubing sets, catheter tip-to-tissue impedance monitoring system, and accessories for cardiac ablation.

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: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 58528

Issued To:

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

NBOG code(s)	Device Name	Intended purpose per IFU
Class III		
--	Inquiry™ Luma-Cath™ Diagnostic Catheter	See CE 60202
--	Therapy™ and Therapy™ Dual-8™ Ablation Catheters using one ablating tip electrode with temperature sensors.	See CE 65957
--	Inquiry™, Inquiry™ Afocus, Inquiry™ Optima™ and Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II Catheters	See CE 69920

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 58528

Issued To:

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

NBOG code(s)	Device Name	Intended purpose per IFU
--	Therapy Cool Path, Therapy Cool Path PLUS, Therapy Cool Path Duo, Therapy Cool Flex, Contact Therapy Cool Flex, Contact Therapy Cool Path, Contact Therapy Cool Path Duo, Therapy Cool Path Triga, Therapy Cool Path Duo Triga, Safire BLU, Safire BLU Duo, Contact Safire BLU and Contact Safire BLU Duo Catheters, Safire Duo Ablation Catheter, MediGuide Enabled and Cool Path Duo Ablation Catheter, MediGuide Enabled	See CE 71046
--	ViewFlex™ Xtra ICE Ultrasound Catheter	See CE 561277

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 58528

Issued To:

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

NBOG code(s)	Device Name	Intended purpose per IFU
Class IIb		
13215	Cool Point Irrigation Pump	The Cool Point irrigation pump is a peristaltic pump that is intended for use in administration of irrigation solution into the patient through an open irrigated ablation catheter. The Cool Point irrigation pump is intended for use only with the Cool Point tubing set.
Class IIa		
MD 0102	Irrigation Pump Tubing set	The Irrigation Pump Tubing Set is a sterile, single use device which provides access for the administration of fluids from a container.
MD 0102	Cool Point Tubing Set	The Cool Point Tubing Set is a sterile and single use device which provides access for the administration of fluids from a container. This tubing set is intended for use with the Cool Point™ Irrigation Pump only.
Class Is		
MD 0106	CE 85222 Annex V – Electrophysiology Cables	--

First Issued: **2001-05-03** Date: **2020-09-06** Expiry Date: **2024-05-26**

...making excellence a habit.™

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 58528**
Date:	**2020-09-06**
Issued To:	**Irvine Biomedical, Inc.** **a St. Jude Medical Company** **2375 Morse Avenue** **Irvine** **California** **92614** **USA**

Subcontractor:	**Service(s) supplied**
Merit Medical Systems Inc 1600 West Merit Parkway South Jordan UT 84095 USA	**Design** **Manufacture** **Regulatory Compliance**
Parter Sterilization Services, LLC 17115 Kingsview Avenue Carson CA 90746 USA	**ETO Sterilization**
St Jude Medical Costa Rica Ltda. Edificio #44, El Coyol Calle 0, Ave. 2, Zona Franca Coyol ALAJUELA Costa Rica	**Manufacture**

...making excellence a habit.™

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 58528**
Date:	**2020-09-06**
Issued To:	**Irvine Biomedical, Inc.** **a St. Jude Medical Company** **2375 Morse Avenue** **Irvine** **California** **92614** **USA**

Subcontractor:	**Service(s) supplied**
St. Jude Medical 14901 DeVeau Place Minnetonka Minnesota 55345-2126 USA	**Manufacture**
St. Jude Medical 5050 Nathan Lane North Plymouth Minnesota 55442 USA	**Manufacture**
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**EU Representative** **Labelling** **Packaging**

...making excellence a habit.™

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 58528**
Date:	**2020-09-06**
Issued To:	**Irvine Biomedical, Inc.** **a St. Jude Medical Company** **2375 Morse Avenue** **Irvine** **California** **92614** **USA**

Subcontractor:	**Service(s) supplied**
Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone El Coyol Alajuela 20102 Costa Rica	**ETO Sterilization**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58528**

Date: **2020-09-06**

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

Date	Reference Number	Action
03 May 2001		First Issue (Transfer of Annex V, Section 3.2 certificate from DGM Certificate Nr. 031, subsequently upgraded to an Annex II, Section 3.2 certificate)
04 January 2002		Cardiac ablation generators added to the scope
16 April 2004		Change of address details
09 July 2004		Addition of sub-contractor, NAmSA
04 May 2006		Addition of Edwards Lifesciences, LLC to the list of subcontractors. Certificate Renewal
12 February 2007		Name changed to include "a St. Jude Medical Company"
20 December 2007		Irrigation pumps and tubing sets added to scope. HEI Inc. and Merit Medical Systems Inc added as subcontractors for manufacture.
24 June 2008	7212459	"Intracardiac catheters used for echocardiography" added to the scope. GE Healthcare added to list of subcontractors for manufacture.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58528**

Date: **2020-09-06**

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

Date	Reference Number	Action
29 July 2009	7430516	Addition of subcontractor, SI. Jude Medical, Minnetonka, MN
28 May 2010	7510842	"Catheter tip-to-tissue impedance monitoring devices" added to the scope. OEM, STERIS Isomedix Services and St. Jude Medical Coordination Center added to the list of significant subcontractors.
15 March 2011	7660787	Certificate Renewal. Correction of history page to add back text reflecting certificate renewal in May 2006. Remove significant subcontractor "GE Healthcare". Reword scope to reflect current activities and devices.
31 October 2011	7731019	Extend the scope to include accessories for cardiac ablation. Add Steris to the list of significant subcontractors for the activity of sterilization. Addition of significant subcontractor St. Jude Medical Cardiovascular Division, Coyol, Costa Rica for manufacturing activities.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58528**

Date: **2020-09-06**

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

Date	Reference Number	Action
11 June 2013	8003586	Addition of St Jude Neuromodulation Division to the list of significant subcontractors. Correct the address of the Costa Rica facility.
16 March 2015	8297445	Addition of Packaging & Labelling to activities of St. Jude Medical Coordination Center BVBA.
31 March 2015	8296211	Addition of Synergy Health, Costa Rica as a significant subcontractor for the ETO sterilization of the Inquiry Catheter Family. The following subcontractors have been discontinued and were removed from the list of significant subcontractors: St. Jude Medical Portland, Steris Libertyville, Sterigenics Salt Lake City, Minnetronix Inc, Steris New Jersey , Edwards Lifesciences LL and HEI Boulder.
15 September 2015	8411946	Addition of significant contractor: SJM Plymouth for receiving inspection and release of Cool Point and irrigation pump tubing sets in addition to Irvine Biomedical.
01 April 2016	8481478	Certificate Renewal. Removed Irvine Biomedical / Irvine CA and OEM / Watertown SD from subcontractor list.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 58528**

Date: **2020-09-06**

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

Date	Reference Number	Action
12 December 2016	8632750	Removal of subcontractor NamSA.
17 March 2017	8690925	'Radiofrequency ablation generators' removed from scope.
05 March 2019	7781598	Traceable to NB 0086.
Current	3266661	Certificate Renewal. Product table added.

bsi.

State of MINNESOTA County of ANOKA Hennepin JW
I certify this to be a complete, exact and true copy of the original document certified this 17th day of April, 2024.
Jennifer L Wilson
JENNIFER L WILSON, Notary Public
My Commission Expires 01/31/2027

JENNIFER L WILSON
Notary Public
State of Minnesota
My Commission Expires
January 31, 2027

Abbott Medical
2375 Morse Avenue
Irvine
California
92614
USA

11 Jul 2023

Notified Body Confirmation Letter

Reference: EU2023-607/654473

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Abbott Medical
2375 Morse Ave
Irvine
California
92614
USA

SRN Number (if available): US-MF-000014304

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written

agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

ChiaLei Ang

Digitally signed by ChiaLei Ang
Date: 2023.07.11 17:55:37 -04'00'

ChiaLei Ang

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Therapy and Therapy Dual-8 Ablation Catheters	Class III	N/A	CE 58528, NB# 2797 CE 65957, NB# 2797
ViewFlex XTRA ICE Catheter	Class III	N/A	CE 58528, NB# 2797 CE 561277, NB# 2797
Inquiry Steerable Diagnostic Catheter	Class III	N/A	CE 58528, NB# 2797 CE 69920, NB# 2797
Inquiry AFocus II Diagnostic Catheter	Class III	N/A	CE 58528, NB# 2797 CE 69920, NB# 2797
Cool Point Irrigation Pump	Class IIb excluding Class IIb implantable non-WET	N/A	CE 58528, NB# 2797
Cool Point Tubing Set	Class IIa	N/A	CE 58528, NB# 2797
Electrophysiology Cables	Class I device placed on the market in sterile condition	N/A	CE 58528, NB# 2797 CE 85222, NB# 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/07/11	Initial issue

ND-RS(1511)

State of MINNESOTA County of [illegible]
I certify this to be a complete, exact and true copy of the original document.
certified this 17th day of April, 2024.
Jennifer L Wilson
JENNIFER L WILSON, Notary Public
My Commission Expires 01/31/2027

ST. JUDE MEDICAL

00141225 Rev. E

JENNIFER L WILSON
Notary Public
State of Minnesota
My Commission Expires
January 31, 2027

Manufacturer's Declaration of Certificate Validity

Manufacturer's Declaration:

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Irvine Biomedical, Inc. a St. Jude Medical Company
Manufacturer address & contact details	2375 Morse Ave Irvine, California, USA 92614
Single Registration Number (SRN) (if available)	Not Issued

Authorised Representative name (if applicable)	St. Jude Medical Coordination Center BVBA
Authorised Representative address and contact details	The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Single Registration Number (SRN) (if available)	BE-AR-000008417

Notified body name (if applicable)	BSI Group the Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified body number (if applicable)	CE 2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Declaration of Certificate Validity

- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate(s)** as listed above or in the attached schedule
  - Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
  - *Choose applicable statements:*

☒ Expired *before* 20 March 2023:

☒ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

☒ Expired/expires *after* 20 March 2023:

☒ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices** ☒ Not Applicable

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

- *Choose one applicable statement:*

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Manufacturer's Declaration of Certificate Validity

- *Choose one applicable statement:*

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☐ A QMS in accordance with Article 10(9) MDR is in place.

  ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:	
Full Company Name:	Irvine Biomedical, Inc. a St. Jude Medical Company
Location & Date:	2375 Morse Avenue Irvine, California 92614, USA
Signature, Print Name, Title:	Abbott Digitally signed by LABAYEX Reason: I am approving this document Date: 2024.03.11 16:28:29 -05'00' Hassan Labay Divisional Vice President, Regulatory Affairs

Manufacturer's Declaration of Certificate Validity

Schedule of Devices

Model Number/ Catalogue number	Product Trade Name	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
IBI-81102	Inquiry™ Steerable Diagnostic Catheter	Design Exam CE 69920 FQA CE 58528	25 Sept 2022	BSI CE 2797	31 Dec 2027	N/A
IBI-81104						
IBI-81105						
IBI-81107						
IBI-81120						
IBI-81124						
IBI-81125						
IBI-81126						
IBI-81130						
IBI-81134						
IBI-81171						
IBI-81172						
IBI-81174						
IBI-81202						
IBI-81207						
IBI-81209						
IBI-81223						
IBI-81224						
IBI-81402						
IBI-81403						
IBI-81404						
IBI-81405						
IBI-81417						
IBI-81418						
IBI-81472						
IBI-81473						
IBI-81474						
IBI-81483						
IBI-81504						
IBI-81516						

Manufacturer's Declaration of Certificate Validity

Model Number/ Catalogue number	**Product Trade Name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
IBI-81530						
IBI-81531						
IBI-81532						
IBI-81534						
IBI-81540						
IBI-81542						
IBI-81721						
IBI-81730						
IBI-81734						
IBI-81736						
IBI-81801						
IBI-81802						
IBI-81807						
IBI-81809						
IBI-81945						
IBI-81947						

Model Number/ Catalogue number	**Product Trade Name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
IBI-87008	Inquiry AFocus II	Design Exam CE 69920 FQA CE 58528	25 Sept 2022	BSI CE 2797	31 Dec 2027	N/A

Manufacturer's Declaration of Certificate Validity

Model Number/ Catalogue number	**Product Trade Name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
IBI-83405	Therapy and Therapy Dual-8 Ablation Catheter	Design Exam CE 65957 FQA CE 58528	26 May 2024	BSI CE 2797	31 Dec 2027	N/A
IBI-83408						
IBI-83510						
IBI-83306						
IBI-83425						
IBI-83516						
IBI-83456						
IBI-83459						
IBI-83701						
IBI-83542						
IBI-83312						
IBI-83702						
IBI-83477						
IBI-83481						
IBI-83308						
IBI-83428						
IBI-83432						
IBI-83351						
IBI-83417						
IBI-83403						
IBI-83309						
IBI-83422						
IBI-83704						
IBI-83543						
IBI-83513						
IBI-83707						
IBI-83302						
IBI-83411						
IBI-83708						
IBI-83453						
IBI-83404						
IBI-83703						

Manufacturer's Declaration of Certificate Validity

Model Number/ Catalogue number	Product Trade Name	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
IBI-83705 IBI-83311						

Model Number/ Catalogue number	Product Trade Name	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
D087031	ViewFlex™ XTRA ICE Catheter	Design Exam CE 561277 FQA CE 58528	26 May 2024	BSI CE 2797	31 Dec 2027	N/A

Model Number/ Catalogue number	Product Trade Name	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
IBI-85641 IBI-85643 IBI-85644 IBI-85684 IBI-85708 IBI-85709 IBI-85711 IBI-85713 IBI-85719 IBI-85735 IBI-85739 IBI-85760	Electrophysiology Cables	FQA CE 58528	26 May 2024	BSI CE 2797	31 Dec 2028	N/A

Manufacturer's Declaration of Certificate Validity

Model Number/ Catalogue number	**Product Trade Name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
IBI-85761						
IBI-85762						
IBI-85763						
IBI-85764						
IBI-85765						
IBI-85769						
A402892						
IBI-85809						
IBI-85930						
IBI-85931						
IBI-85942						
IBI-85945						
IBI-85953						
IBI-85954						
IBI-85955						
IBI-89002						
IBI-85201						
IBI-85205						

Model Number/ Catalogue number	**Product Trade Name**	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**Notified Body name and number**	**End date of extended validity/transition period**	**Substitute Device** (if applicable)
85785	Cool Point™ Tubing Set	FQA CE 58528	26 May 2024	BSI CE 2797	31 Dec 2028	N/A
85784	Cool Point™ Irrigation Pump					

ND-RS(1512)

SJM Declaration of Conformity
Cool Point Tubing Set

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 2007/42/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 Avenue 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:	Tubing Set
Product Name(s):	Cool Point™ Tubing Set,
Model and Model Number(s):	85785
Classification:	Class IIa, Rule 2 according to Annex IX of the MDD 93/42/EEC
GMDN Code(s):	44772
Original CE Mark Date:	21 December 2007
EC Certificate No and expiration date:	Certificate No: CE 58528 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 7781595)

Signature:

Adam Ettl
Manager, Regulatory Affairs

23 Sep 2020
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

making excellence a habit.™

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. Barbatului 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.