Product Highlights

- Color-coded cables available for easy identification
- Guided channel for fast, convenient connection
- Clearly labeled terminal pins

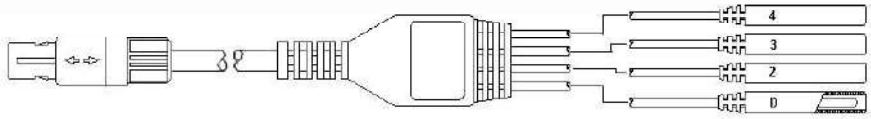
Ordering Information

Diagnostic connecting cable (1 unit per box)

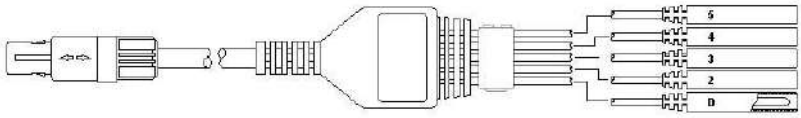
Reorder Number	Model Number	Description	Usable Length (cm)
85953	1904-SA	4-Pin Diagnostic Connecting Cable	1.5
85954	1910-SA	10-Pin Diagnostic Connecting Cable	1.5
85930	1910-S	10-Pin Diagnostic Connecting Cable	1.5
85942	1910-S	10-Pin Diagnostic Connecting Cable	2.5
85955	1914-SA	14-Pin Diagnostic Connecting Cable	1.5
85931	1924-S	24-Pin Diagnostic Connecting Cable	1.5

Note: “SA” means “Shrouded Autoclavable” cable

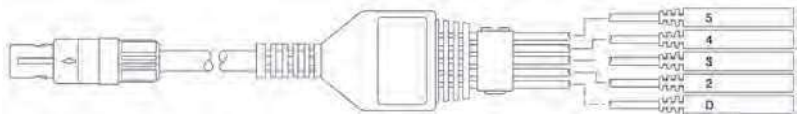
1904-SA



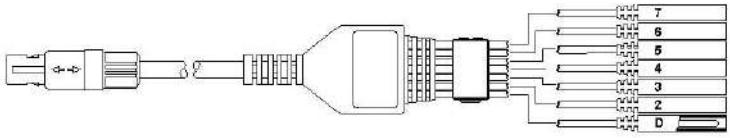
1910-SA



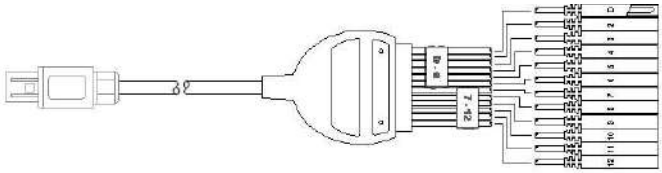
1910-S



1914-SA



1924-S



bsi.

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

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.

bsi.

By Royal Charter

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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By Royal Charter

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**

...making excellence a habit.™

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.

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:

Legal Manufacturer
Adam Ettl
Regulatory Affairs Manager

08 Jul 2019
Issue Date

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
Issue Date

Legal Manufacturer
Adam Etti
Regulatory Affairs Manager

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:*

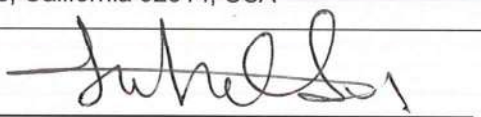
  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☐ 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:	 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						
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		Design Exam CE 69920 FQA CE 58528	25 Sept 2022	BSI CE 2797	31 Dec 2027	N/A
IBI-81207	Inquiry™ Steerable Diagnostic Catheter					
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	[redacted]					
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	Electrophysiology Cables	FQA CE 58528	26 May 2024	BSI CE 2797	31 Dec 2028	N/A
IBI-85643						
IBI-85644						
IBI-85684						
IBI-85708						
IBI-85709						
IBI-85711						
IBI-85713						
IBI-85719						
IBI-85735						
IBI-85739						
IBI-85760						

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					

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

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

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. Bratului 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.