

Product Highlights

- Variable electrode spacing for pacing and recording
- Multiple curve configurations for ease of placement
- Push/pull handle for steering control
- 1 mm band electrodes

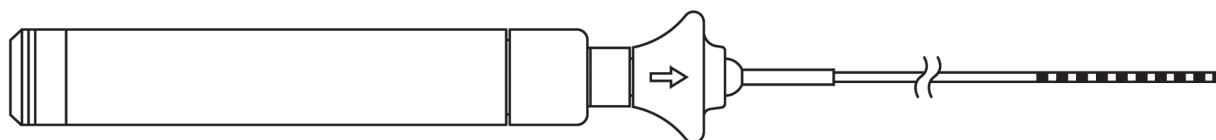
Ordering Information

5 F Decapolar steerable diagnostic catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Curve Type	Usable Length (cm)
81171	1110-5-2-M	2	1	Medium	110
81172	1110-5-25-M	2-5-2	1	Medium	110
81174	1110-5-25-L	2-5-2	1	Large	110
81223	1110-5-2(50)3-XL	2(50)3	1	X-Large	110
81734	1110-5-25-L (soft)	2-5-2	1	Large	110
81735	1110-5-5-L (soft)	5	1	Large	110
81736	1110-5-5(22)5-M/L (soft)	5(22)5	1	Medium/Large	110
81721	1110-5-25-M(SC) (soft)	2-5-2	1	Medium(SC)	110
81730	1110-5-28-M/L (soft)	2-8-2	1	Medium/Large	110

Required Catheter Connecting Cables – Page 122

Reorder Number	Model Number	Description	Length (m)
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



Product Highlights

- Variable electrode spacing for pacing and recording
- Multiple curve configurations for ease of placement
- Push/pull handle for steering control
- Bi-directional Steering model

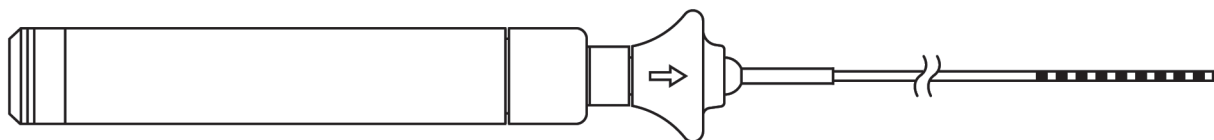
Ordering Information

6 F Decapolar steerable diagnostic catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
81102	1110-6-25-M	2-5-2	Medium	110
81104	1110-6-25-L	2-5-2	Large	110
81105	1110-6-25-XL	2-5-2	X-Large	110
81107	1110-6-5-L	5	Large	110
81520	1110-6-2-XL-TE4BE4	2	X-Large	110
81524	1110-6-2-L-TE4BE4	2	Large	110
87006	1110-6-25-M/L(SOFT)	2-5-2	Medium/Large	110
81945	1110-6-25-L(SOFT)	2-5-2	Large	110
81947	1110-6-5-M/L(SOFT)	5	Medium/Large	110
81504	1110-6-5-M-TE2BE2-BD	5	Medium	110

Required Catheter Connecting Cable – Page 122

Reorder Number	Model Number	Description	Length (m)
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



EC Design-Examination Certificate

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

No.**CE 69920****Issued To:**

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

In respect of:

Inquiry™, Inquiry™ Afocus, Inquiry™ Optima™ and Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II 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: 2002-09-26**Date: 2017-09-22****Expiry Date: 2022-09-25**

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Page 1 of 6

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 certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 69920

Issued To:

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

Diagnostic Catheters
Inquiry™ Fixed Curve Diagnostic Catheters
Model Numbers: 10XX ⁽¹⁾ -X ⁽²⁾ -X ⁽³⁾ - X ⁽⁴⁾ - X ⁽⁵⁾
Inquiry™ Steerable Diagnostic Catheters
Model Numbers: 11XX ⁽¹⁾ -X ⁽²⁾ - X ⁽³⁾ - X ⁽⁴⁾ -X ⁽⁵⁾

Cardioversion Catheters
Inquiry™ Fixed Curve Cardioversion Catheters
Model Numbers: 10XX ⁽¹⁾ -CV-X ⁽²⁾ -X ⁽³⁾ - X ⁽⁴⁾ - X ⁽⁵⁾
Inquiry™ Steerable Cardioversion Catheters
Model Numbers: 11XX ⁽¹⁾ -CV-X ⁽²⁾ - X ⁽³⁾ - X ⁽⁴⁾ -X ⁽⁵⁾

Notes
XX ⁽¹⁾ – defines the number of electrodes, from 1 to 30
X ⁽²⁾ – is the outside diameter in French size, from 4Fr to 7Fr
X ⁽³⁾ – is the electrode spacing, these are variable
X ⁽⁴⁾ – defines the curve configuration. For Cardioversion Catheters, curve configurations include "C", "C1", "SC1", "L" and two additional shapes

First Issued: **2002-09-26**

Date: **2017-09-22**

Expiry Date: **2022-09-25**

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- X⁽⁵⁾ – various modifiers including but not limited to:
- Useable length is specified if it's not 110cm (from 60 cm to 130 cm)
 - TE"X" – tip electrode length where "X" is between 1 mm to 4 mm
 - BE"X" – band electrode length where "X" is between 0.6 mm to 4 mm
 - POS – Pin out Shrouded
 - SOFT – Soft tube
 - AF – AFocus
 - OPT - Optima
 - AB – all braided tubing
 - EB – extended braid tubing
 - BD – bi-directional steering
 - DL – double loop
 - H"X"(40-50 mm nominal) – H-Curve TV Steerable Diagnostic Catheter curve configurations include H, HJ, and four additional shapes

CV designates Cardioversion

First Issued: **2002-09-26**

Date: **2017-09-22**

Expiry Date: **2022-09-25**

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EC Design-Examination Certificate

Supplementary Information to CE 69920

Issued To:

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2375 Morse Avenue
Irvine
CA 92614
USA**

Certificate History

Date	Reference Number	Action
26 September 2002	10039964	First Issue
21 August 2003	10051238	Addition of Inquiry™ with 0.6 mm band electrodes
09 July 2004	10059218	Change of address New certificate format
20 August 2004	10061093	Inquiry™ Optima™ and Bi-directional catheters added to the scope
23 January 2006	10072850	Addition of Inquiry™ Cardioversion Catheters
13 March 2006	10078316	Inquiry™ Optima™ PLUS Diagnostic Catheter added to the scope
12 October 2006	10080300	Inquiry Cardioversion II Catheters added to the scope
12 February 2007	10083251	Name change to include "a St. Jude Medical Company"
17 August 2007	10089753	Certificate renewal
27 September 2007	10091579	Removal of the reference 'IBI' throughout the certificate
27 June 2008	10098262	Addition of "All Braid" shaft to the Inquiry™ Catheters. Clarify modification code X(5) to be more specific.
16 September 2008	10098977	Addition of Inquiry™ H-Curve TV Steerable Diagnostic Catheters

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2375 Morse Avenue
Irvine
CA 92614
USA**

Certificate History

Date	Reference Number	Action
27 May 2009	10104367	Expansion of list of defibrillators that are compatible with the Inquiry™ cardioversion catheter 1400-CV and 1400-CV-II cardioversion catheters to include the Medtronic® Lifepak 20 and Philips HeartStart XL biphasic defibrillators
25 September 2012	10136624	Certificate renewal.
21 May 2013	10141030	Addition of St. Jude Medical Costa Rica Ltda as an alternative manufacturing site for the Inquiry Steerable Diagnostic Catheter.
31 March 2015	10154190	Synergy Health, Costa Rica added as a significant subcontractor for the ETO sterilization of the Inquiry Catheter Family.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
Current	8760902	Certificate renewal.

First Issued: **2002-09-26**

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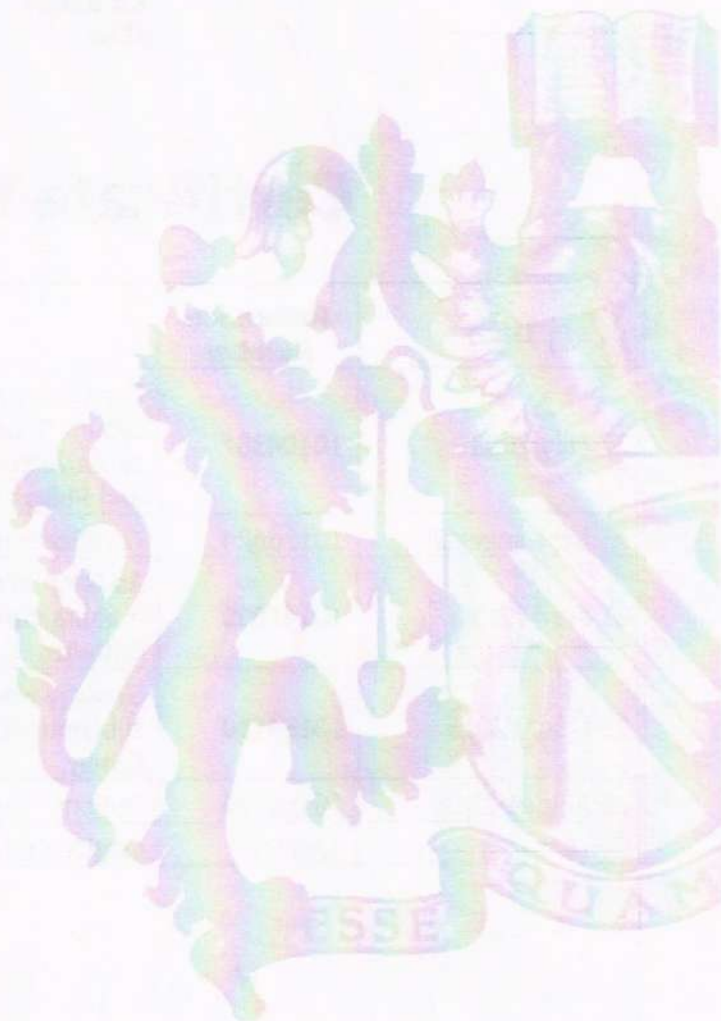
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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**SJM Declaration of Conformity****Inquiry™, Inquiry™ AFocus™, Inquiry™ Optima, Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II Catheters**

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. 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:

Diagnostic Catheters

Product Name(s):

Inquiry™, Inquiry™ AFocus™, Inquiry™ Optima, Inquiry™ Optima™ PLUS Diagnostic Catheters and Inquiry™ Cardioversion and Cardioversion II Catheters

Model and Model Number(s):

Diagnostic Catheters
Inquiry™ Fixed Curve Diagnostic Catheter
10XX⁽¹⁾ - X⁽²⁾ - X⁽³⁾ - X⁽⁴⁾ - X⁽⁵⁾

Inquiry™ Steerable Diagnostic Catheter
11XX⁽¹⁾ - X⁽²⁾ - X⁽³⁾ - X⁽⁴⁾ - X⁽⁵⁾

Cardioversion Catheters
Inquiry™ Fixed Curve Cardioversion Catheter
10XX⁽¹⁾ - CV - X⁽²⁾ - X⁽³⁾ - X⁽⁴⁾ - X⁽⁵⁾

Inquiry™ Steerable Cardioversion Catheter
11XX⁽¹⁾ - CV - X⁽²⁾ - X⁽³⁾ - X⁽⁴⁾ - X⁽⁵⁾

Notes:

XX⁽¹⁾ – defines the number of electrodes, from 1 to 30

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- X⁽⁵⁾ – various modifiers including but not limited to:
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 - BD - bi-directional steering
 - DL – double loop
 - H"X"(40-50 mm nominal) – H-Curve TV Steerable Diagnostic Catheter curve configurations include H, HJ, and four additional shapes

CV designates Cardioversion

Classification: Class III, Rule 7 according to Annex IX of the MDD 3/42/EEC.

GMDN Code(s): 46355

Original CE Mark Date: 26 Sep 2002

EC Certificate No: Certificate No: 69920
Expiration Date: 25 Sep 2022

Applicable Quality System Standards: ISO 13485:2003

Notified Body: BSI
Kitemark Court
Davy Avenue
Knowlhill, Milton Keynes
MK5 8PP UK

Notified Body Number: 0086

Signature:


Kellie Stefaniak
Manager, Regulatory Affairs


Issue Date

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

Latest Revision Date: 2022-03-22

Effective Date: 2021-12-14

Expiry Date: 2024-12-13

Page: 1 of 1



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CERTIFICATE



This is to certify that



SANTE
INTERNATIONAL S.A.

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. Brailului 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.