

Therapy™ Cool Path™ Ablation Catheters
4 mm Tip Thermocouple
Quadripolar
7 F

Irrigated Ablation Catheters

Product Highlights

- All braided shaft
- Double mesh stainless steel braiding to the distal tip
- Six equidistant ports on the distal tip
- Uni-directional steering
- Push/pull handle

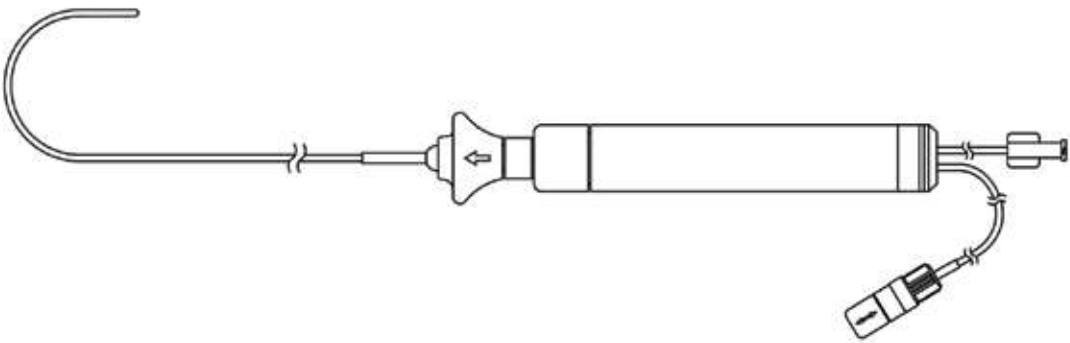
Ordering Information

7 F irrigated ablation catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type	Usable Length (cm)
83502	1304-CP-7-25-L-AB	2-5-2	4	2	Large	110
83503	1304-CP-7-25-M-AB	2-5-2	4	2	Medium	110
83504	1304-CP-7-25-XL-AB	2-5-2	4	2	X-Large	110
83505	1304-CP-7-25-L1-AB	2-5-2	4	2	Large1	110
83506	1304-CP-7-25-FL-AB	2-5-2	4	2	Flutter	110

Required Catheter Connecting Cable – Page 164

SJM: 85641



Therapy™ Cool Path™
Duo Ablation Catheters
4 mm Tip Thermocouple
Quadripolar
7 F

Irrigated Ablation Catheters

Product Highlights

- All braided shaft
- Double mesh stainless steel braiding to the distal tip
- Two rows of six equidistant ports offset by 30 degrees
- Proximal and distal tip electrode irrigation
- Uni-directional steering
- Push/pull handle

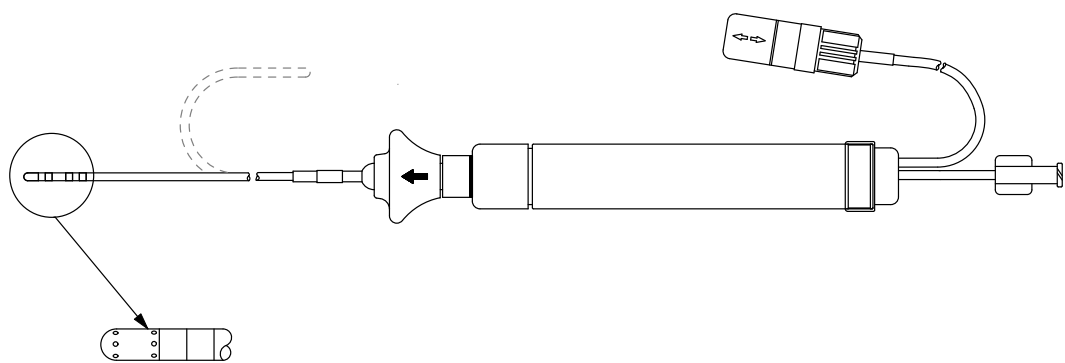
Ordering Information

7 F irrigated ablation catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Tip Electrode (mm)	Band Electrode (mm)	Curve Type
83562	1304-CP2-7-1.5(5)2-M-TE4BE1AB	1.5-5-2	4	1	Medium
83563	1304-CP2-7-1.5(5)2-L-TE4BE1AB	1.5-5-2	4	1	Large
83564	1304-CP2-7-1.5(5)2-XL-TE4BE1AB	1.5-5-2	4	1	X-Large
83565	1304-CP2-7-1.5(5)2-L1-TE4BE1AB	1.5-5-2	4	1	Large1

Required Catheter Connecting Cable – Page 164

SJM: 85641, 85644



EC Design-Examination Certificate

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

No.**CE 71046****Issued To:**


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

In respect of:

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

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 1 of 10

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, 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.

EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Therapy Cool Path Ablation Catheter, Therapy Cool Path Duo Ablation Catheter and Contact Therapy Cool Path Duo Ablation Catheters

Model No:	Notes
Therapy Cool Path Ablation Catheter 130X ⁽¹⁾ -CP-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾	(1) = up to 4 total electrodes including Electrodes made of Pt/Ir (90/10) 1 ablation tip and 3 band electrodes (maximum) Tip electrode length from 2mm – 4mm Band electrode width from 1mm – 2mm
Therapy Cool Path Duo Ablation Catheter 130X ⁽¹⁾ -CP2-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾	(2) = Outside Diameter: 7 French Catheter body material – PEBAX
Contact Therapy Cool Path Duo Ablation Catheter 130X ⁽¹⁾ -CP2-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾ -CN	(3) = Interelectrode Spacing from 1mm – 35mm which may include 1 reference band electrode up to 50 cm from the tip
Therapy Cool Path Duo X ⁽⁶⁾ Ablation Catheter 130X ⁽¹⁾ -CP2-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾	(4) = various curve configurations between the smallest curve (S) and the largest curve (XL) and "NS" for "Non-Steerable". Pull wire design (non-flat wire) will be designated as follows: (4) = various curve configurations between the smallest curl ("MC") and largest curl ("LC"); and, smallest sweep ("MS") and largest sweep ("LS")

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 2 of 10

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

	<p>(5) = various modifiers including but not limited to:</p> <ul style="list-style-type: none"> • Useable length may be specified other than 110cm or 115cm (for the 'NS') • Number of temperature sensors – (1) • TE"X" – tip electrode length where "X" is between 2mm to 4mm • BE"X" – band electrode length where "X" is between 1mm to 2mm • TH – thermistor temperature sensor (otherwise, default is "TC" thermocouple sensor) • AB – all braided tubing • EB – extended braid tubing • ST – spring stiffness • BD – bi-directional steering • CN – Contact enabled <p>(6) = SP - devices packaged in straight packaging configuration (applicable for bi-directional irrigated catheters)</p>
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First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Safire BLU Duo Ablation Catheter

Model No:	Notes
Safire BLU Duo X ⁽⁶⁾ Ablation Catheter 130X ⁽¹⁾ -CP2S-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾	(1) = up to 4 total electrodes including Electrodes made of Pt/Ir (90/10) 1 ablation tip and 3 band electrodes (maximum) Tip electrode length from 2mm – 4mm Band electrode width from 1mm – 2mm
	(2) = Outside Diameter: 7 French Catheter body material – PEBAX
	(3) = Interelectrode Spacing from 1mm – 35mm which may include 1 reference band electrode up to 50 cm from the tip
	Pull wire design (non-flat wire) will be designated as follows: (4) = various curve configurations between the smallest curl ("MC") and largest curl ("LC"); and, smallest sweep ("MS") and largest sweep ("LS")
	(5) = various modifiers including but not limited to: <ul style="list-style-type: none"> • Useable length may be specified other than 110cm or 115cm (for the 'NS') • Number of temperature sensors – (1) • TE"X" – tip electrode length where "X" is between 2mm to 4mm • BE"X" – band electrode length where "X" is between 1mm to 2mm • TH – thermistor temperature sensor (otherwise, default is "TC" thermocouple sensor) • AB – all braided tubing • EB – extended braid tubing • ST – spring stiffness • BD – bi-directional steering
	(6) = SP - devices packaged in straight packaging configuration (applicable for bi-directional irrigated catheters)

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 4 of 10

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EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Therapy Cool Flex Ablation Catheter

Model Number	Notes
Therapy Cool Flex Ablation Catheter: 130X(1)-CF-X(2)-X(3)-X(4)-X(5)	(1) = up to 4 total electrodes including Electrodes made of Pt/Ir (90/10) 1 ablation tip and 3 band electrodes (maximum) Tip electrode length from 2mm - 4mm Band electrode width from 1mm - 2mm
	(2) = Outside Diameter 7 French Catheter body material - PEBAX
	(3) = Interelectrode Spacing from 0.5mm - 35mm which may include 1 reference band electrode up to 50 cm from the tip
	(4) = various curve configurations between the smallest curve (S) and the largest curve (XL) and "NS" for "Non-Steerable"
	(5) = various modifiers including but not limited to: <ul style="list-style-type: none"> • Useable length may be specified other than 110 cm or 115 cm (for the "NS") • Number of temperature sensors - (1) • TE"X" - tip electrode length where "X" is from 2mm to 4mm • BE"X" - band electrode length where "X" is from 1mm to 2mm • TH- thermistor temperature sensor (otherwise, default is "TC" thermocouple sensor) • AB - all braided tubing • EB - extended braid tubing • ST - spring stiffness • BD - bi-directional steering

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 5 of 10

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A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Safire Duo Ablation Catheter, MediGuide Enabled and Cool Path Duo Ablation Catheter, MediGuide Enabled

Model Number	Notes
Safire Duo Ablation Catheter, MediGuide Enabled 130X ⁽¹⁾ -CP2S-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾ -ME	(1) = Up to 4 total electrodes includes electrodes made of Pt/Ir (90/10) <ul style="list-style-type: none"> One ablation tip and three band electrodes (maximum) Tip electrode length of 4mm Band electrode width is 2mm
Cool Path Duo Ablation Catheter, MediGuide Enabled 130X ⁽¹⁾ -CP2-X ⁽²⁾ -X ⁽³⁾ -X ⁽⁴⁾ -X ⁽⁵⁾ -ME	(2) = Outside diameter of 8 French Catheter body material - PEBAX
	(3) = Interelectrode spacing from 2mm – 5mm
	(4) = Various curve configurations between the smallest curl (MC) and the largest curl (LC); and the smallest sweep (MS) and the largest sweep (LS).
	(5) = Various modifiers including but not limited to: <ul style="list-style-type: none"> BD – Bi-Directional Steering RA – Uni-Directional Steering with Return Assist

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Certificate History

Date	Reference Number	Action
08 May 2003	10044323	First Issue
28 April 2004	10054488	Adding 2mm Catheter tip to the existing 4mm, addition of a thermistor option and the material of the Luer lock to polycarbonate. Also change of business address
09 July 2004	10059218	Change of address New certificate format
21 March 2005	10066592	Product name changed to "IBI Therapy Cool Path Ablation Catheters" from "Cooled-Tip Ablation Catheters"
26 May 2006	10079000	Minor changes to the design of the product
12 February 2007	10083251	Name changed to include "a St. Jude Medical Company"
27 June 2007	10088505	Change to certificate, limitations on the wild cards.
29 October 2007	10091902	Add Cool Path Duo catheters and the trade name Cool Path Plus for Cool Path catheters with 5-8 electrodes
28 March 2008	10095699	Certificate renewal. Update product codes and names on certificate
30 May 2008	10096909	Addition of Non-Steerable ("NS") designs to the Cool Path product lines.

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Certificate History

Date	Reference Number	Action
03 September 2008	10098665	Addition of Therapy Cool Path Triga and Therapy Cool Path Duo Triga product lines
17 December 2008	10100750	Addition of Therapy Cool Path Triga and Therapy Cool Path Duo Triga with 7.5 French distal tips.
09 June 2009	10105557	Addition of Contact Therapy Cool Path and Contact Therapy Cool Path Duo to scope and associated catalogue codes to supplementary pages
29 July 2009	10108468	Addition of new line extensions for pull wire design: Safire BLU, Safire BLU Duo, Contact Safire BLU, Contact Safire BLU Duo, Cool Path, Cool Path Duo, Contact Cool Path and Contact Cool Path Duo: these designs will have various curve configurations between the smallest curl ("MC") and largest curl ("LC"); and, smallest sweep ("MS") and largest sweep ("LS")
20 February 2010	10110714	Addition of Therapy Cool Flex and Contact Therapy Cool Flex line extensions. Correct typographically error for Safire Blu devices to change under note (1),* from "Cool Path" to "Safire Blu"

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Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 8 of 10

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Issued To:

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

Certificate History

Date	Reference Number	Action
23 April 2012	10135390	Line extension to include Safire Duo Ablation Catheter, MediGuide Enabled and Cool Path Duo Ablation Catheter, MediGuide Enabled
15 August 2012	10136236	Review of packaging change from a coiled hoop configuration to a straight package for the: Cool Path Duo, Contact Cool Path Duo, Safire BLU Duo, and Contact Safire BLU Duo Ablation Catheter families. Minor, non significant updates to the IFU clarifying the single use statement, clarification of symbols used, and update of device names to include "SP" which denotes the use of the "Straight Package".
07 May 2013	10141057	Certificate Renewal
10 June 2015	10156225	Tip shaft buckle force product specification change.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 9 of 10

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.

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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.

EC Design-Examination Certificate

Supplementary Information to CE 71046

Issued To:

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

Certificate History

Date	Reference Number	Action
27 April 2018	8903170	Certificate Renewal. Clarification of product names for consistency. Removal of the following product families: Therapy Cool Path PLUS, Contact Therapy Cool Flex, Contact Therapy Cool Path, Therapy Cool Path Triga, Therapy Cool Path Duo Triga, Safire BLU, Contact Safire BLU, Contact Safire BLU Duo, Therapy Cool Path and Therapy Cool Path PLUS (Bi-Directional), Contact Therapy Cool Path and Contact Therapy Cool Path Duo (Bi-Directional).
Current	7781598	Traceable to NB 0086.

First Issued: **2003-05-08**

Date: **2019-03-05**

Expiry Date: **2023-05-07**

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Page 10 of 10

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.

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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.



SJM Declaration of Conformity
Therapy Cool Path Ablation Catheter, Therapy Cool Path Duo Ablation Catheter, and
Contact Therapy Cool Path Duo Ablation Catheter

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: Electrophysiology and Ablation Catheters

Product Name(s): Therapy Cool Path Ablation Catheter
Therapy Cool Path Duo Ablation Catheter
Contact Therapy Cool Path Duo Ablation Catheter

Signature:


Legal Manufacturer
Jennifer Ruether
Manager, Regulatory Affairs


Issue Date



Model and Model Number(s):

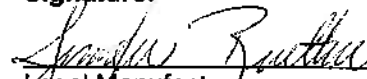
Therapy Cool Path Ablation Catheter
130X⁽¹⁾-CP-X⁽²⁾-X⁽³⁾-X⁽⁴⁾-X⁽⁵⁾

Therapy Cool Path Duo Ablation Catheter
130X⁽¹⁾-CP2-X⁽²⁾-X⁽³⁾-X⁽⁴⁾-X⁽⁵⁾

Contact Therapy Cool Path Duo Ablation Catheter
130X⁽¹⁾-CP2-X⁽²⁾-X⁽³⁾-X⁽⁴⁾-X⁽⁵⁾-CN

Notes:
(1) = Up to 4 total electrodes including Electrode made of Pt/Ir (90/10) 1 ablation tip and 3 band electrodes (maximum) Tip electrode length from 2mm – 4mm Band electrode width from 1mm – 2mm
(2) = Outside Diameter: 7 French Catheter body material – Pebax
(3) = Interelectrode spacing from 1mm – 35mm which may include 1 reference band electrode up to 50 cm from the tip
(4) = various curve configurations between the smallest curve (S) and the largest curve (XL) and "NS" for "Non-Steerable". Pull wire design (non-flat wire) will be designated as follows: (4) = Various curve configuration between the smallest curl (MC) and the largest curl (LC); and the smallest sweep (MS) and the largest sweep (LS).
(5) = Various modifiers including but not limited to: <ul style="list-style-type: none"> • Useable length may be specified other than 110cm or 115cm (for the 'NS') • Number of temperature sensors – (1) • TE"X" – tip electrode length where "X" is between 2mm to 4mm • BE"X" – band electrode length where "X" is between 1mm to 2mm • TH – thermistor temperature sensor (otherwise, default is "TC" thermocouple sensor) • AB – all braided tubing • EB – Extended braid tubing • ST – spring stiffness • BD – Bi-Directional Steering • CN – Contact enabled

Signature:


Legal Manufacturer
Jennifer Ruether
Manager, Regulatory Affairs


Issue Date



Classification: Class III, Rule 7 according to Annex IX of the MDD 93/42/EEC.

GMDN Code(s): 61785

Original CE Mark Date: 8 May 2003

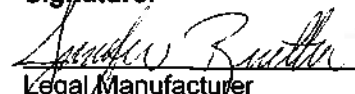
EC Certificate No and expiration date: Certificate No: CE 71046
Expiration Date: 7 May 2023

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)

Signature:


Legal Manufacturer
Jennifer Ruether
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. Botevului 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
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