Inquiry™ Electrophysiology Catheters
Decapolar
5 F

Steerable Diagnostic

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

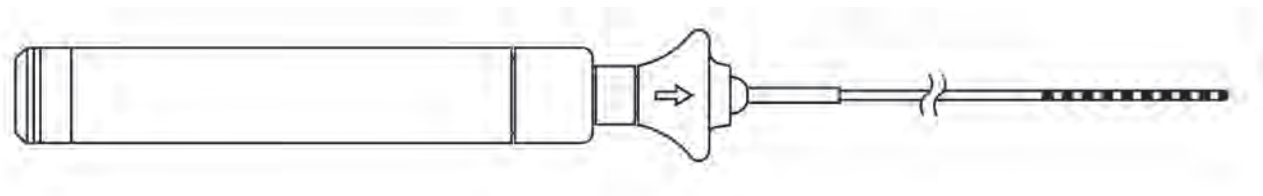
Ordering Information

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



ST. JUDE MEDICAL

Inquiry™ Electrophysiology Catheters
Decapolar
6 F

Steerable Diagnostic

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

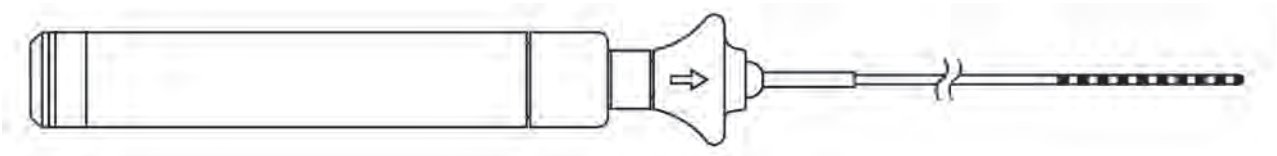
Ordering Information

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



ST. JUDE MEDICAL

By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 751167 R000

Manufacturer: Abbott Medical

Address:
2375 Morse Avenue
Irvine
California
92614
USA

Single Registration Number: US-MF-000014304

EU Authorised Representative: Abbott Medical

Address:
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 751167 R000

Device Schedule:

Device Name: Inquiry™ Steerable Diagnostic Catheter

Intended Purpose per IFU: The Inquiry™ steerable electrophysiology catheters are intended for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
Inquiry™ Steerable Diagnostic Catheter	IBI-81102	MDN 1203	Class III	5414734DMS0011HQ
	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			

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 751167 R000

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
Inquiry™ Steerable Diagnostic Catheter	IBI-81405	MDN 1203	Class III	5414734DMS0011HQ
	IBI-81417			
	IBI-81418			
	IBI-81472			
	IBI-81473			
	IBI-81474			
	IBI-81483			
	IBI-81504			
	IBI-81516			
	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			

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 751167 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3449049	Issued

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 751164 R000

Manufacturer: Abbott Medical

Address:
2375 Morse Avenue
Irvine
California
92614
USA

Single Registration Number: US-MF-000014304

EU Authorised Representative: Abbott Medical

Address:
The Corporate Village
Da Vincilaan 11 Box F1
1935
Zaventem
Belgium

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 751164 R000

Device Schedule: Class III devices

Class III, Non Implantable	Intended purpose
Inquiry™ Steerable Diagnostic Catheter	See MDR 751167

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 751164 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3449046	Issued

First Issued: **2022-07-08** Date: **2022-07-08** Expiry Date: **2027-07-07**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation 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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 751164 R000

Date: **2022-07-08**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	**Labelling** **Packaging**
Abbott Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2, Zona Franca Coyol El Coyol Alajuela Costa Rica	**Manufacture**
Parter Sterilization Services A Division of Parter Medical Products 17115 Kingsview Avenue Carson California 90746 USA	**ETO Sterilization**
St. Jude Medical 2305 Walnut Street Roseville Minnesota 55113 USA	**Labelling** **Packaging**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 751164 R000

Date: **2022-07-08**

Critical Subcontractor/Crucial Supplier	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**

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2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5000
Fax: 949-769-5144

00117144 Rev. A

MDR Declaration of Conformity

Manufacturer:	Abbott Medical
Manufacturer SRN:	US-MF-000014304
Address:	2375 Morse Avenue Irvine, CA 92614 USA
Manufacturing Site(s):	Abbott Medical 2375 Morse Avenue Irvine, CA 92614 USA Abbott Medical Costa Rica Ltda. Edificio #44 Calle 0, Ave. 2, Zona Franca El Coyol, Alajuela Costa Rica
European Authorized Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
European Authorized Representative SRN:	BE-AR-000008744

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Type:	Diagnostic Catheter
Product Trade Name(s):	Inquiry™ Steerable Diagnostic Catheter
Model Number(s):	See attached product list
Product Trade Name(s):	Inquiry™ Steerable Diagnostic Catheter
Model Number(s):	See attached product list
Intended Purpose:	The Inquiry™ steerable electrophysiology catheters are intended for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies
Risk Classification:	MDR per Annex VIII

Signature: Kristin Ruffner Senior Director, Clinical and Regulatory Affairs	25 July 2022 Issue Date On behalf of Abbott Medical, signed at St. Paul, MN

2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5000
Fax: 949-769-5144

00117144 Rev. A

MDR Declaration of Conformity

Classification Rationale:	Chapter III Section 5, Rule 7, Sub part 1
EMDN Code(s):	C020104
Basic UDI-DI:	5414734DMS0011HQ

The products described in this declaration are in conformity with all applicable EU harmonized legislation, including:

- Regulation (EU) 2017/745, and the applicable *General Safety & Performance Requirements* in Annex 1
- Medical Device Directive, 93/42/EEC, and the applicable provisions of Annex 1

Common Specifications Applied:	EN ISO 13485:2016
STED #	0000042579
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Kaynesplein 9 1066 EP Amsterdam The Netherlands Notified Body Number: 2797
Supporting Certificate(s):	Quality Management System Certificate: MDR 751164 Expiration Date: 07JUL 2027 Technical Documentation Assessment: MDR 751167 Number> Expiration Date: 07JUL 2027
Original CE Mark Date:	26 SEP 2002
Conformity Assessment:	Annex IX, Chapter I, II, III

2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5000
Fax: 949-769-5144

00117144 Rev. A

MDR Declaration of Conformity

Device Photograph:	

2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5000
Fax: 949-769-5144

MDR Declaration of Conformity

The products in the attached Declaration of Conformity Product List are approved under MDR TDAC Certificate MDR 751167.

Declaration of Conformity Product List

Model Number	Product Description	UDI-DI
IBI-81102	1110-6-25-M	5414734DMS0011HQ
IBI-81104	1110-6-25-L	5414734DMS0011HQ
IBI-81105	1110-6-25-XL	5414734DMS0011HQ
IBI-81107	1110-6-5-L	5414734DMS0011HQ
IBI-81120	1120-7-17-H	5414734DMS0011HQ
IBI-81124	1124-7-271-H	5414734DMS0011HQ
IBI-81125	1110-7-291-H	5414734DMS0011HQ
IBI-81126	1110-7-291-HL	5414734DMS0011HQ
IBI-81130	1120-7-19-HL	5414734DMS0011HQ
IBI-81134	1124-7-291-HL	5414734DMS0011HQ
IBI-81171	1110-5-2-M	5414734DMS0011HQ
IBI-81172	1110-5-25-M	5414734DMS0011HQ
IBI-81174	1110-5-25-L	5414734DMS0011HQ
IBI-81202	1120-7-2-10-XXL	5414734DMS0011HQ
IBI-81207	1120-7-5-SL	5414734DMS0011HQ
IBI-81209	1120-7-25-SL	5414734DMS0011HQ
IBI-81223	1110-5-2(50)3-XL	5414734DMS0011HQ
IBI-81224	1110-5-2(30)3-M	5414734DMS0011HQ
IBI-81402	1104-6-25-M	5414734DMS0011HQ
IBI-81403	1104-6-5-M	5414734DMS0011HQ
IBI-81404	1104-6-25-L	5414734DMS0011HQ
IBI-81405	1104-6-5-L	5414734DMS0011HQ
IBI-81417	1104-6-5-XL	5414734DMS0011HQ
IBI-81418	1104-6-25-XL	5414734DMS0011HQ
IBI-81472	1104-5-25-M	5414734DMS0011HQ
IBI-81473	1104-5-5-M	5414734DMS0011HQ
IBI-81474	1104-5-25-L	5414734DMS0011HQ
IBI-81483	1104-5-5-E(HIS) (SOFT)	5414734DMS0011HQ
IBI-81504	1110-6-5-M-TE2BE2-BD	5414734DMS0011HQ
IBI-81516	1108-6-25-L1-BD-TE2BE1(SOFT)	5414734DMS0011HQ
IBI-81530	1110-4-2-M	5414734DMS0011HQ
IBI-81531	1110-4-25-M	5414734DMS0011HQ
IBI-81532	1110-4-25-L	5414734DMS0011HQ
IBI-81534	1110-4-5-L	5414734DMS0011HQ
IBI-81540	1104-4-25-M	5414734DMS0011HQ
IBI-81542	1104-4-5-M	5414734DMS0011HQ
IBI-81721	1110-5-25-M(SC) (SOFT)	5414734DMS0011HQ
IBI-81730	1110-5-28-M/L (SOFT)	5414734DMS0011HQ
IBI-81734	1110-5-25-L (SOFT)	5414734DMS0011HQ
IBI-81736	1110-5-5(22)5-M/L (SOFT)	5414734DMS0011HQ

The signature is applied on page 1

2375 Morse Avenue
Irvine, CA 92614
Tel: 949-769-5000
Fax: 949-769-5144

00117144 Rev. A

MDR Declaration of Conformity

Model Number	Product Description	UDI-DI
IBI-81801	1108-6-2-M	5414734DMS0011HQ
IBI-81802	1108-6-25-M	5414734DMS0011HQ
IBI-81807	1108-6-2-L	5414734DMS0011HQ
IBI-81809	1108-6-25-L	5414734DMS0011HQ
IBI-81945	1110-6-25-L (SOFT)	5414734DMS0011HQ
IBI-81947	1110-6-5-M/L (SOFT)	5414734DMS0011HQ

The signature is applied on page 1

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No: **FM 728657**

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

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

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

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CERTIFICATE

This is to certify that

SANTE INTERNATIONAL S.A.

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

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

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

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

ISO 9001 : 2015

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

DQS GmbH

Markus Bleher
Managing Director

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

Annex to certificate
Registration No. 497269 QM15

SANTE INTERNATIONAL S.A.

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

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

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