



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, 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: See Table below

Product Name(s): See Table below

Model and Catalogue Number(s):

Model, Type	Catalogue Number	Product Name
1010-6-28-SC, Fixed Curve Diagnostic Catheter	IBI-80003	Inquiry™ Fixed Curve Diagnostic Catheter
1008-6-5(45)25-J1-TE1BE2(SOFT), Fixed Curve Diagnostic Catheter	IBI-80043	
1010-5-28-SC, Fixed Curve Diagnostic Catheter	IBI-80063	
1010-5-28-SC(60CM), Fixed Curve Diagnostic Catheter	IBI-80064	
1010-6-28-SC (SOFT), Fixed Curve Diagnostic Catheter	IBI-80139	
1010-6-28-SC-TE2BE2(65)(SOFT), Fixed Curve Diagnostic Catheter	IBI-80142	
1004-6-5-C-4BE, Fixed Curve Diagnostic Catheter	IBI-80250	
1004-6-5-J-4BE, Fixed Curve Diagnostic Catheter	IBI-80251	
1004-6-10-C-4BE, Fixed Curve Diagnostic Catheter	IBI-80253	
1004-6-10-J-4BE, Fixed Curve Diagnostic Catheter	IBI-80254	
1004-6-25-J, Fixed Curve Diagnostic Catheter	IBI-80405	
1004-6-5-J, Fixed Curve Diagnostic Catheter	IBI-80406	
1004-6-5-C, Fixed Curve Diagnostic Catheter	IBI-80409	
1004-6-5-D, Fixed Curve Diagnostic Catheter	IBI-80412	



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1004-6-10-J, Fixed Curve Diagnostic Catheter	IBI-80413	
1004-5-5-C(HIS) (SOFT), Fixed Curve Diagnostic Catheter	IBI-80440	
1004-5-25-J, Fixed Curve Diagnostic Catheter	IBI-80452	
1004-5-5-J, Fixed Curve Diagnostic Catheter	IBI-80453	
1004-5-5-C, Fixed Curve Diagnostic Catheter	IBI-80456	
1004-4-5-C, Fixed Curve Diagnostic Catheter	IBI-80465	
1004-4-25-C, Fixed Curve Diagnostic Catheter	IBI-80466	
1004-4-5-J, Fixed Curve Diagnostic Catheter	IBI-80468	
1004-4-25-J, Fixed Curve Diagnostic Catheter	IBI-80469	
1004-6-5-C(HIS) (SOFT), Fixed Curve Diagnostic Catheter	IBI-80515	
1004-4-5-C(HIS), Fixed Curve Diagnostic Catheter	IBI-80567	
1004-6-5-J1-TE2BE2, Fixed Curve Diagnostic Catheter	IBI-80570	
1010-5-5(20)-C1-TE2BE2, Fixed Curve Diagnostic Catheter	IBI-80571	
1004-5-5-D-TE2BE2, Fixed Curve Diagnostic Catheter	IBI-80575	
1006-5-5-J1 (SOFT), Fixed Curve Diagnostic Catheter	IBI-80627	
1008-6-2-C, Fixed Curve Diagnostic Catheter	IBI-80804	
1110-6-25-M, Steerable Diagnostic Catheter	IBI-81102	✓
1110-6-25-L, Steerable Diagnostic Catheter	IBI-81104	✓
1110-6-25-XL, Steerable Diagnostic Catheter	IBI-81105	✓
1110-6-5-L, Steerable Diagnostic Catheter	IBI-81107	✓
1120-7-17-H, Steerable Diagnostic Catheter	IBI-81120	
1121-7-17-H-SC, Steerable Diagnostic Catheter	IBI-81121	
1124-7-271-H, Steerable Diagnostic Catheter	IBI-81124	
1110-7-291-H, Steerable Diagnostic Catheter	IBI-81125	
1110-7-291-HL, Steerable Diagnostic Catheter	IBI-81126	
1120-7-19-HL, Steerable Diagnostic Catheter	IBI-81130	
1124-7-291-HL, Steerable Diagnostic Catheter	IBI-81134	

Inquiry™
Steerable
Diagnostic
Catheter






1120-7-5-HL-UP, Steerable Diagnostic Catheter	IBI-81136	
1120-6-17-HJ (SOFT), Steerable Diagnostic Catheter	IBI-81144	
1110-5-2-M, Steerable Diagnostic Catheter	IBI-81171	✓
1110-5-25-M, Steerable Diagnostic Catheter	IBI-81172	✓
1110-5-25-L, Steerable Diagnostic Catheter	IBI-81174	✓
1110-6-2-L1-TE2BE2, Steerable Diagnostic Catheter	IBI-81199	
1120-7-2-10-XXL, Steerable Diagnostic Catheter	IBI-81202	
1120-7-5-SL, Steerable Diagnostic Catheter	IBI-81207	
1120-7-25-SL, Steerable Diagnostic Catheter	IBI-81209	
1120-6-13-L1, Steerable Diagnostic Catheter	IBI-81213	
1120-6-13-M1, Steerable Diagnostic Catheter	IBI-81214	
1120-6-5-HSE(95), Steerable Diagnostic Catheter	IBI-81221	
1110-5-2(50)3-XL, Steerable Diagnostic Catheter	IBI-81223	✓
1110-5-2(30)3-M, Steerable Diagnostic Catheter	IBI-81224	
1110-6-25-XL1, Steerable Diagnostic Catheter	IBI-81226	
1104-6-25-M, Steerable Diagnostic Catheter	IBI-81402	
1104-6-5-M, Steerable Diagnostic Catheter	IBI-81403	
1104-6-25-L, Steerable Diagnostic Catheter	IBI-81404	
1104-6-5-L, Steerable Diagnostic Catheter	IBI-81405	
1104-6-5-XL, Steerable Diagnostic Catheter	IBI-81417	
1104-6-25-XL, Steerable Diagnostic Catheter	IBI-81418	
1104-5-25-M, Steerable Diagnostic Catheter	IBI-81472	
1104-5-5-M, Steerable Diagnostic Catheter	IBI-81473	
1104-5-25-L, Steerable Diagnostic Catheter	IBI-81474	
1104-5-5-E(HIS) (SOFT), Steerable Diagnostic Catheter	IBI-81483	
1104-6-5-L1-TE2BE2, Steerable Diagnostic Catheter	IBI-81491	
1110-6-5-M-TE2BE2-BD, Steerable Diagnostic Catheter	IBI-81504	✓



1108-6-25-L1-BD-TE2BE1(SOFT), Steerable Diagnostic Catheter	IBI-81516	
1110-6-2-XL-TE4BE4, Steerable Diagnostic Catheter	IBI-81520	✓
1105-5-5(170)-M/L-TE1BE2 (SOFT), Steerable Diagnostic Catheter	IBI-81521	
1110-6-2-L-TE4BE4, Steerable Diagnostic Catheter	IBI-81524	✓
1110-5-2(170)170-C1(HIS)- TE2BE2(95), Steerable Diagnostic Catheter	IBI-81526	
1110-4-2-M, Steerable Diagnostic Catheter	IBI-81530	✓
1110-4-25-M, Steerable Diagnostic Catheter	IBI-81531	✓
1110-4-25-L, Steerable Diagnostic Catheter	IBI-81532	✓
1110-4-5-L, Steerable Diagnostic Catheter	IBI-81534	✓
1110-4-25-M(SC)(60) , Steerable Diagnostic Catheter	IBI-81537	✓
1104-4-25-M, Steerable Diagnostic Catheter	IBI-81540	
1104-4-5-M, Steerable Diagnostic Catheter	IBI-81542	
1104-4-25-L, Steerable Diagnostic Catheter	IBI-81543	
1110-5-3(170)50-M, Steerable Diagnostic Catheter	IBI-81557	
1106-6-5-E, Steerable Diagnostic Catheter	IBI-81603	
1110-5-25-M(SC) (SOFT), Steerable Diagnostic Catheter	IBI-81721	✓
1110-5-28-M/L (SOFT), Steerable Diagnostic Catheter	IBI-81730	✓
1110-5-25-L (SOFT), Steerable Diagnostic Catheter	IBI-81734	✓
1110-5-5-L (SOFT), Steerable Diagnostic Catheter	IBI-81735	✓
1110-5-5(22)5-M/L (SOFT), Steerable Diagnostic Catheter	IBI-81736	✓
1107-5-25(170)-L1, Steerable Diagnostic Catheter	IBI-81762	
1108-6-2-M, Steerable Diagnostic Catheter	IBI-81801	
1108-6-25-M, Steerable Diagnostic Catheter	IBI-81802	
1108-6-2-L, Steerable Diagnostic Catheter	IBI-81807	
1108-6-25-L, Steerable Diagnostic Catheter	IBI-81809	
1108-5-2-M, Steerable Diagnostic Catheter	IBI-81871	



1108-5-25-M, Steerable Diagnostic Catheter	IBI-81872	
1110-6-25-L (SOFT), Steerable Diagnostic Catheter	IBI-81945	✓
1110-6-5-M/L (SOFT), Steerable Diagnostic Catheter	IBI-81947	✓
1110-5-5-AF20, Diagnostic Catheter	IBI-81674	Inquiry™ AFocus™ Diagnostic Catheter
1120-7-1(2.5)-SM-AF20, Diagnostic Catheter	IBI-81587	Inquiry™ AFocus II™ Diagnostic Catheter
1114-7-14-SM-AF15-BE.6, Diagnostic Catheter	IBI-81590	
1110-7-3.5-SM-AF15, Diagnostic Catheter	IBI-81594	
1110-7-5-SM-AF20, Diagnostic Catheter	IBI-81595	
1110-7-27-SM-AF20, Diagnostic Catheter	IBI-81596	
1110-7-8-SM-AF25, Diagnostic Catheter	IBI-81599	
1110-5-5-SM-AF20, Diagnostic Catheter	IBI-81673	
1110-5-3.5-SM-AF15, Diagnostic Catheter	IBI-81680	
1120-7-1(7)-SM-AF20DL, Diagnostic Catheter	IBI-87007	
1120-7-4-SM-AF20DL, Diagnostic Catheter	IBI-87008	
1110-7-5-SM-AF20EB, Diagnostic Catheter	D087022	
1110-7-3-SM-AF15EB, Diagnostic Catheter	D087023	
1120-7-1(2.5)-SM-AF20EB, Diagnostic Catheter	D087024	
1120-7-1(4.5)-SM-OPT25-EB, Diagnostic Catheter	IBI-81659	
1120-7-1(7)-SM-OPT30EB, Diagnostic Catheter	IBI-81664	
1120-7-1(4.5)-SM-OPT25, Diagnostic Catheter	IBI-81683	
1110-7-7-SM-OPT25, Diagnostic Catheter	IBI-81687	
1110-7-7-SM-OPT25EB, Diagnostic Catheter	IBI-81767	
1124-7-1(4.5)(20)(3)-SM-OPT25, Diagnostic Catheter	IBI-81717	Inquiry™ Optima™ PLUS Diagnostic Catheter
1010-CV-6-5-J-TE4BE4, Cardioversion Catheter	IBI-80993	Inquiry™ Cardioversion Fixed Curve Catheter



1110-CV-6-2-L-TE4BE4, Cardioversion Catheter	IBI-81997	Inquiry™ Cardioversion Steerable Catheter
1114-CV-7-3(80)3-L-TE4BE4, Cardioversion Catheter	IBI-81998	

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

GMDN Code(s): 46355

Original CE Mark Date: 26 Sep 2002

EC Certificate No and expiration date: Certificate No: CE 69920
Expiration Date: 25 Sep 2022

Applicable Quality System Standards: ISO 13485:2016

Notified Body: BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Notified Body Number: 2797 (Traceable to NB number 0086, BSI Reference 7781598)

Signature:



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Legal Manufacturer
Adam Ettl
Manager, Regulatory Affairs

Issue Date




Product Highlights

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

Ordering Information

6 F steerable diagnostic catheter (1 unit per box)

Reorder Number	Description	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
81402	1104-6-25-M	2-5-2	Medium	110
81403	1104-6-5-M	5	Medium	110
81404	1104-6-25-L	2-5-2	Large	110
81405	1104-6-5-L	5	Large	110
81417	1104-6-5-XL	5	X-Large	110
81418	1104-6-25-XL	2-5-2	X-Large	110

Required Catheter Connecting Cable – Page 122

Reorder Number	Model Number	Description	Length (m)
85953	1904-SA	4-Pin Diagnostic Connecting Cable	1.5

