

## SJM Declaration of Conformity Therapy™ and Therapy™ Dual-8™ Ablation 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:** Ablation Catheters

**Product Name(s):** Therapy™ Ablation Catheter and Therapy™ Dual-8™ Ablation Catheter

**Model No.:** Therapy™ and Therapy™ Dual-8™ Ablation Catheters using one ablation tip electrode with temperature sensors  
13XX<sup>(1)</sup>-X<sup>(2)</sup>-XX<sup>(3)</sup>-X<sup>(4)</sup>-XX X<sup>(5)</sup>-BD<sup>(6)</sup>

**Notes:**

- (1) – Number of electrode, from 1 to 14
- (2) – Outside Diameter in French size, 5Fr to 9Fr
- (3) – Interelectrode spacing, these are variable
- (4) – Curve configuration
- (5) – Modification Code (specifies usable length, tip/band electrode length, and the number of temperature sensors)
- (6) – BD designation will only be present on bi-directional deflection catheters

Model	Catalogue Number	Product Name
1304-7-25-M-TE8	IBI-83302	Therapy™ Ablation Catheter
1304-7-25-L-TE8	IBI-83306	
1304-7-25-L-TE8A	IBI-83309	
1304-7-25-XL-TE8A	IBI-83311	
1304-7-25-XL-TE8	IBI-83312	
1304-5-25-M-TE4BE1(SOFT)	IBI-83351	
1304-5-2-S-TE4BE1	IBI-83403	
1304-7-2-M	IBI-83404	
1304-7-25-M	IBI-83405	
1304-7-25-L	IBI-83408	
1304-7-25-E	IBI-83411	
1304-7-25-XL	IBI-83417	
1304-7-25-S	IBI-83432	
1304-7-25-S-TH	IBI-83453	

1304-7-25-M-TH	IBI-83456		
1304-7-25-L-TH	IBI-83459		
1304-7-25-M-TE8-TH	IBI-83474		
1304-7-25-L-TE8-TH	IBI-83477		
1304-7-25-XL-TE8-TH	IBI-83481		
1304-7-25-M-TF	IBI-83510		
1304-7-25-S-TF	IBI-83513		
1304-7-25-L-TF	IBI-83516		
1304-7-25-M-TH-TF(90)	IBI-83552		
1304-7-25-M-BD	IBI-83701		
1304-7-25-L-BD	IBI-83702		
1304-7-25-S-BD	IBI-83703		
1304-7-25-L-TE8-BD	IBI-83704		
1304-7-25-XL-BD	IBI-83705		
1304-7-25-M-TE8-BD	IBI-83707		
1304-7-25-XL-TE8-BD	IBI-83708		
1304-7-25-L-TE8TC2A	IBI-83308		Therapy™ Dual-8™ Ablation Catheter
1304-7-25-M-TE8TC2	IBI-83422		
1304-7-2-L-TE8TC2	IBI-83424		
1304-7-25-L-TE8TC2	IBI-83425		
1304-7-25-XL-TE8TC2	IBI-83428		
1304-7-25-L-TE8TC2-TF	IBI-83542		
1304-7-25-XL-TE8TC2-TF	IBI-83543		
1304-7-25-M-TE8TC2-TF	IBI-83545		

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

**GMDN Code(s):** 61785

**Original CE Mark Date:** 27 May 2002

**EC Certificate No and expiration date:** Certificate No: CE 65957  
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)

**Signature:**

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Legal Manufacturer  
Adam Ettl  
Manager, Regulatory Affairs

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Issue Date