

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 639058

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN 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: 2015-08-19

Latest Revision Date: 2022-04-20

Effective Date: 2021-12-14

Expiry Date: 2024-12-13

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