

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Heraeus Medical Components Caribe
415 Road 693, Km. 7.3
Dorado
00646-4802
Puerto Rico

Holds Certificate No:

FM 76401

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The contract manufacture, assembly, and machining of components for cardiac electrophysiology devices such as pacemakers.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 08/06/2004

Latest Revision Date: 03/22/2016

Effective Date: 05/01/2016

Expiry Date: 02/28/2019

Page: 1 of 1



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