

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

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 13485:2016 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:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-08-06

Latest Revision Date: 2019-03-25

Effective Date: 2019-05-01

Expiry Date: 2022-04-30

Page: 1 of 1



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