

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Heraeus Medical Components, LLC
5030 Centerville Road
St Paul
Minnesota
55127
USA

Holds Certificate Number:

FM 703008

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture and distribution of finished Retrieval Snares, Guidewires and Catheters for Vascular and Non-Vascular use (sterile and non-sterile).

Design, development, and production of medical device components and assemblies, finished Neuromodulation leads, Implantable Pulse Generators, Guidewires and Catheters.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-01-18

Latest Revision Date: 2025-07-18

Effective Date: 2025-07-28

Expiry Date: 2028-07-27

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