

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Heraeus Medical Components, SRL
Zona Franca La Lima
Cartago
30106
Costa Rica

Holds Certificate Number:

FM 739011

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

Manufacture and distribution of sterile and non-sterile nitinol and stainless steel guidewires, sterile and non-sterile retrieval snares and retrieval snare kits, non-sterile neuromodulation leads, sterile and nonsterile transeptal needle/dilator and sheath.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-10-29

Latest Revision Date: 2025-06-03

Effective Date: 2025-07-28

Expiry Date: 2028-07-27

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