

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Biorep Technologies, Inc.
15804 NW 57th Avenue
Miami Lakes
Florida
33014
USA

Holds Certificate Number:

FM 588156

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

Design, manufacture, service and distribution of sterile cardiovascular devices and sterile surgical instruments for general hospital use. Contract services for design, manufacturing, manual and automated assembly, distribution, sterilization management, process validation for medical devices, and regulatory services.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2012-10-23

Latest Revision Date: 2024-04-25

Effective Date: 2022-12-10

Expiry Date: 2025-12-09

Page: 1 of 1



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