

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nextern Costa Rica Limited

La lima Free Zone Park
Multitenant 2, Module 4
Cartago Guadalupe
Cartago
Costa Rica

Holds Certificate Number:

FM 757604

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

Contract manufacturing, warehousing, testing and sterile and non-sterile barrier packaging of integrated systems active pneumatic devices, mechanical hand steerable body insertion medical devices, and active pulse generating medical devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-06-10

Latest Revision Date: 2025-03-27

Effective Date: 2025-06-10

Expiry Date: 2028-06-09

Page: 1 of 1



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