

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

**Nextern Inc.**  
**dba Nextern Innovation, LLC**  
10601 Fountains Drive  
Maple Grove  
Minnesota  
55369  
USA

Holds Certificate Number:

FM 677060

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

Design, Development, Contract Manufacturing, Testing, Sterilization and Warehousing of integrated system (electro- mechanical) pneumatic and pulse generating medical equipment and therapy delivery (electro-mechanical and mechanical only) hand steerable body insertion devices.

For and on behalf of BSI:

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Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2017-01-27

Latest Revision Date: 2025-05-24

Effective Date: 2023-08-25

Expiry Date: 2026-08-24

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