

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Sheathing Technologies, Inc.

675 Jarvis Drive
Morgan Hill
California
95037
USA

Holds Certificate Number:

MD 815968

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

The design and development, manufacturing and distribution of sterile and non-sterile ultrasound probe covers; sterile procedure kits and gel-filled probe cover, and sterile and non-sterile ultrasound coupling gel.

Transfer from NSAI
Certificate number: CM19.3576/A

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-17

Latest Revision Date: 2025-02-17

Effective Date: 2025-02-17

Expiry Date: 2026-08-27

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