

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

NovelCath
8609 Xylon Ct. N.
Minneapolis
Minnesota
55445
USA

Holds Certificate Number: MD 795250

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

NovelCath provides design support services to their customers, prototype development, manufacturing of catheter delivery systems, alloy and polymer fabrication of precision medical components.

Transfer from: NQA
Certificate number: 18558

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-10-20

Latest Revision Date: 2023-10-30

Effective Date: 2023-10-20

Expiry Date: 2026-04-28

Page: 1 of 1



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