

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Innovative Catheter Solutions Ltd
Unit 2
Ballybrit Business Park
Galway
H91 DT7C
Ireland

Holds Certificate Number:

MD 722885

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

Contract design and development, cleanroom manufacturing and packaging of catheters, introducer sheaths, delivery systems, sub-assemblies, tubing and components to customer specifications intended for terminal sterilization.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-02-11

Latest Revision Date: 2022-05-19

Effective Date: 2021-02-11

Expiry Date: 2024-02-10



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