

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Arrotek Medical Limited
Finisklin Business Park
Sligo
Ireland

Holds Certificate Number:

MD 96205

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

Contract design, development, manufacture and packaging of sterile and non-sterile plastic-based medical devices: needles, sheaths, catheters, introducers, handles, dilators, leads and delivery systems to customer specifications.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2005-08-11

Latest Revision Date: 2023-08-02

Effective Date: 2023-08-11

Expiry Date: 2026-08-10

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