

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-08-11

Latest Revision Date: 2020-08-07

Effective Date: 2020-08-11

Expiry Date: 2021-02-10

Page: 1 of 1



003

...making excellence a habit.™