

# 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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2005-08-11

Latest Revision Date: 2019-10-30

Effective Date: 2017-08-11

Expiry Date: 2020-08-10

Page: 1 of 1



003

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