

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Arrotek Medical Limited
Collooney Business Park
Collooney
Sligo
Ireland

Holds Certificate Number:

MD 96205

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Contract design and manufacture of non-sterile plastic-based needles, sheaths, catheters, introducers, handles, dilators 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: 2017-08-10

Effective Date: 2017-08-11

Expiry Date: 2019-02-28

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