

Certificate of Registration

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

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 13485:2016 & 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: 2018-08-10

Effective Date: 2017-08-11

Expiry Date: 2020-08-10

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Location

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Registered Activities

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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