



## 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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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <a href="mailto:online">online</a>. Printed copies can be validated at <a href="https://www.bsigroup.com/ClientDirectory">www.bsigroup.com/ClientDirectory</a>