

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Creagh Medical Ltd.
IDA Business Park
Ballinasloe
Galway
H53 K8P4
Ireland

Facility ID Number: F007685

Holds Certificate No:

MDSAP 815696

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

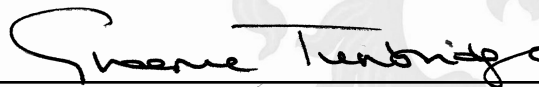
Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2024-10-22

Effective Date: 2024-10-22

Expiry Date: 2027-03-11



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 815696**

Registered Scope:

Design, Development and Production of Percutaneous Transluminal Angioplasty and Percutaneous Transluminal Coronary Angioplasty Catheters; Drug Coating and Production of Drug Coated Balloon Catheters.

Transfer from TUV SUD

Certificate Number: QS6 074222 0014 Rev. 03



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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.