ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 074222 0014 Rev. 03

Certificate Holder: **Creagh Medical Ltd**
IDA Business Park
Ballinasloe, Co Galway, H53 K8P4
IRELAND

Certification Mark:

Scope of Certificate: **Design, Development and Production of Percutaneous Transluminal Angioplasty and Percutaneous Transluminal Coronary Angioplasty Catheters; Drug Coating and Production of Drug Coated Balloon Catheters**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 074222 0014 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F004520**
Report No.: **75960189**
Effective Date: **2024-03-12**
Expiry Date: **2027-03-11**

Date of Issue: 2024-03-18

(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 074222 0014 Rev. 03

Regulatory Requirements: **Audit/Certification Criteria**

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

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

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Creagh Medical Ltd**
IDA Business Park, Ballinasloe, Co Galway, H53 K8P4, IRELAND

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