



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Sedana Medical Limited Unit 2A The Village Centre Twomilehouse Naas Kildare Ireland

Facility ID Number: F003373

Holds Certificate No:

**MDSAP 706954** 

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

The design, manufacture and distribution of anaesthetic agents delivery systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-09-12

Effective Date: 2022-04-27

Expiry Date: 2025-04-26

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MEDICAL DEVICE SINGLE AUDIT PROGRAM BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

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