

# 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 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



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 1

...making excellence a habit.™