

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 736312 R000

**Manufacturer:** Sedana Medical Limited

**Address:**

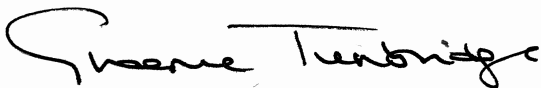
Unit 2A  
The Village Centre  
Two Mile House  
Naas  
Kildare  
W91PWH5  
Ireland

**Single Registration Number:** IE-MF-000001734

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2022-08-26**

Date: **2022-08-26**

Expiry Date: **2027-08-25**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Anaesthetic delivery systems	Class IIa



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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3291368	Issued



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## List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

### MDR 736312 R000

Date: 2022-08-26

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Innovatif Cekal Sdn. Bhd. No 35 Jalan HJ. Abdul Karim 53 Kampung Jawa, Off Jalan Sungai Jati Klang Selangor 41200 Malaysia	Manufacture

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