By Royal Charter

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 667826**

Issued To: **Sedana Medical Limited**
**Unit 2A, The Village Centre,**
**Twomilehouse**
**Naas**
**Co.Kildare, W91 PWH5**
**Ireland**

In respect of:

**The design and manufacture of anaesthetic delivery systems and associated syringes.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-02-09** Date: **2021-03-05** Expiry Date: **2024-05-26**

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# EC Certificate - Full Quality Assurance System

**Supplementary Information to CE 667826**

Issued To:

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**Unit 2A, The Village Centre,**
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**Ireland**

| NBOG code(s) | Device description | Intended purpose |
|---|---|---|
| **Class IIa** | | |
| MD 1102 | Anaesthetic delivery system | Not required for Class IIa |
| MD 1102 | Accessories for Anaesthetic delivery system | Not required for Class IIa |

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

# List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

| | |
|---|---|
| Certificate No: | **CE 667826** |
| Date: | **2021-03-05** |
| Issued To: | **Sedana Medical Limited**<br>**Unit 2A, The Village Centre,**<br>**Twomilehouse**<br>**Naas**<br>**Co.Kildare, W91 PWH5**<br>**Ireland** |

| **Subcontractor:** | **Service(s) supplied** |
|---|---|
| FROHE Sp. z o.o.<br>Ryszarda Chomicza 1<br>55-080 Nowa Wies Wroclawska<br>Polska<br>Poland | **Manufacture** |
| Innovatif Cekal Sdn. Bhd.<br>No 35 Jalan HJ. Abdul Karim 53<br>Kampung Jawa, Off Jalan Sungai Jati<br>Klang<br>Selangor<br>41200<br>Malaysia | **Manufacture** |
| Pentaferte Italia S.r.l.<br>Via Modena 119<br>Ferrara<br>44122<br>Italy | **Crucial Supplier** |

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 667826**

Date: **2021-03-05**

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| Date | Reference Number | Action |
|---|---|---|
| 09 February 2017 | 8676173 | First issue. The devices were previously CE-marked by Sedana Medical AB under certificate CE 94203. |
| 07 March 2019 | 8936374 | Traceable to NB 0086. |
| 23 April 2020 | 3144657 | Certificate Renewal.<br>Device table added. Legal Manufacturer address corrected to include the EIR code – W91 PWH5. |
| 05 March 2021 | 3334567 | Administrative change to remove device names "AnaConDa" and "AnaConDa S" from the scope and device table. |
| **Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3** | | |
| 03 September 2021 | 3443906 | Amended - FROHE Sp. z o.o. added as critical subcontractor for manufacturing. |

Inspiring trust for a more resilient world.

03 September 2021

Sedana Medical Limited
Twomilehouse
Co.Kildare, W91 PWH5
Naas
Ireland

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

| Certificate | Directive and Annex | Reference Number | Changes approved |
|---|---|---|---|
| CE 667826 | 90/385/EEC Annex 2 excluding Section 4 | 3443906 | FROHE Sp. z o.o. added as critical subcontractor for manufacturing. NBOG code for Accessories for anaesthetic delivery system shall be MD 0101 within the device table. This has been left uncorrected as MDD certificates are not allowed to be changed during the transition period. |

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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