

# 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  
Kildare  
Ireland**

In respect of:

**The design and manufacture of the AnaConDa 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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 February 2017**Date: **09 February 2017**Expiry Date: **26 April 2020**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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## List of Significant Subcontractors

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

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**Subcontractor:**

**Service(s) supplied**

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Innovatif Cekal Sdn. Bhd.  
No 35 Jalan HJ. Abdul Karim 53  
Kampung Jawa, Off Jalan Sungai Jati  
Klang  
Selangor  
41200  
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**Manufacture**

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Pentaferte Italia S.r.l.  
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**Crucial Supplier**

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## Certificate History

**Certificate No:** CE 667826  
**Date:** 09 February 2017  
**Issued To:** Sedana Medical Limited  
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 Twomilehouse  
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 Ireland

Date	Reference Number	Action
09 February 2017	8676173	First issue. The devices were previously CE-marked by Sedana Medical AB under certificate CE 94203.

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