

# EC Certificate - Full Quality Assurance System

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

**No.** CE 670456  
**Issued To:** **Inogen, Inc.**  
**326 Bollay Drive**  
**Goleta**  
**California**  
**93117**  
**USA**

In respect of:

**Design and manufacture of portable and stationary oxygen concentrator systems and accessories for patients requiring supplemental oxygen.**

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):



Albert Roossien, Regulatory Lead

First Issued: **2017-05-19**

Date: **2019-03-22**

Expiry Date: **2022-05-18**

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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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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	<b>EU Representative</b>
Inogen, Inc. 1225 Commerce Drive Richardson Texas 75081 USA	<b>Manufacture</b>
Salter Labs 100 W. Sycamore Road Arvin California 93203 USA	<b>Manufacture</b>

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# EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
19 May 2017	8707997	Initial issue.
Current	8814868	Traceable to NB 0086.

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