By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 602728**

Issued To: **Inovo, Inc.**
401 Leonard Blvd N
Lehigh Acres
Florida
33971
USA

In respect of:

Design, development and manufacture of oxygen regulator and conserving devices

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: **2013-12-13** Date: **2019-11-21** Expiry Date: **2023-12-31**

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Supplementary Information to CE 602728

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Number	Device Name	Intended purpose per IFU
Class IIb		
12873	Bonsai Series Pneumatic Oxygen Conserver	Intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplement oxygen in their home and for ambulatory use.
12873	Evolution Series Electronic Oxygen Conserver	Intended for prescription use only to be used as part of a portable oxygen delivery system for patients that require supplement oxygen in their home and for ambulatory use.

First Issued: **2013-12-13** Date: **2019-11-21** Expiry Date: **2023-12-31**

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List of Significant Subcontractors

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

Certificate No:	**CE 602728**
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Subcontractor:	**Service(s) supplied**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 602728**

Date: **2019-11-21**

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Date	Reference Number	Action
13 December 2013	8030066	First Issue and Certificate Renewal. Transfer from another Notified Body.
28 November 2018	9625398	Certificate Renewal.
21 February 2019	8210751	Traceable to NB 0086.
Current	3050547	Update to device table to remove specific model no. OM-810.