By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 502901**

Issued To: **Ohio Medical, LLC**
1111 Lakeside Drive
Gurnee
Illinois
60031
USA

In respect of:

The design and manufacture of suction and oxygen therapy products and low-pressure hose assemblies for use with medical gases

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: **2006-01-12** Date: **2020-02-01** Expiry Date: **2024-05-26**

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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 502901**
Date:	**2020-02-01**
Issued To:	**Ohio Medical, LLC** **1111 Lakeside Drive** **Gurnee** **Illinois** **60031** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502901**
Date: **2020-02-01**
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60031
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Date	Reference Number	Action
12 January 2006	4781661	First Issue.
11 December 2007	7145805	Addition of subcontractor Inovo Inc for the activity of manufacture.
21 December 2010	7475137 7596012	Extension to scope to include oxygen monitors. Addition of EU representative to the list of significant subcontractors. Certificate renewal.
05 September 2011	7719275	Addition of Mine Safety Appliances Co. to the list of significant subcontractors for manufacture.
27 February 2014	8026146	Scope extended to include digital vacuum regulators (analogue versions already within scope). Oxygen monitoring devices removed from scope along with corresponding subcontractor, Mine safety Appliances Co.
07 January 2016	8436588	Amended Subcontractor details (Inovo inc.). Removal of 'products' from the scope. Certificate renewal.
11 March 2016	8485334	Change name from, 'Ohio Medical Corporation' to 'Ohio Medical, LLC.' Removal of subcontractor, 'Inovo Incorporated' from the certificate. Repaired typo in EU rep's address from Buisiness Park to Business Park.

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Date	Reference Number	Action
5 February 2018	8863792	Added hose assemblies to scope.
1 March 2019	7781908	Traceable to NB 0086.
10 June 2019	9715124	Change to EU representative: removal of Oxygen Care Ltd, addition of Emergo Europe.
Current	3008616	Certificate renewal.