

# 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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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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**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

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**USA**

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 Buisness 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.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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