

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.

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: **12 January 2006**

Date: **11 March 2016**

Expiry Date: **11 January 2021**

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Page 1 of 1

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

Oxygen Care Ltd.
2 Holfeld Business Park
Kilmacanogue
Co Wicklow
Ireland

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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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 Buisness Park to Business Park.