

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.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 502901**
 Date: **2020-02-01**
 Issued To: **Ohio Medical, LLC**
1111 Lakeside Drive
Gurnee
Illinois
60031
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.
01 February 2020	3008616	Certificate renewal.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
18 October 2024	30288336	Removed Subcontractor pages. Added significant subcontractor.

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18 October 2024

Ohio Medical, LLC
1111 Lakeside Drive
Gurnee
Illinois
60031
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 502901	93/42/EEC Annex II excluding Section 4	30288336	Removed Subcontractor pages. Added significant subcontractor for assembly and testing of vacuum regulators.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices