

EC Certificate - Full Quality Assurance System

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

No. CE 01554
Issued To: **Bio-Med Devices**
61 Soundview Road
Guilford
Connecticut
06437
USA

In respect of:

The design, development and manufacture of ventilators, oxygen blenders and breathing circuits.

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: **27 February 1997**

Date: **06 February 2017**

Expiry Date: **26 February 2022**

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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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Subcontractor:

Service(s) supplied

Medical Market I.N.T. AB
Sehlstedtsgatan 6
Stockholm
115 28
Sweden

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01554**
 Date: **06 February 2017**
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 61 Soundview Road
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Date	Customer Reference	Action
27 February 1997		Original issue
14 May 2002		Change of scope – addition of breathing circuits 5 year certificate renewal
27 March 2003		Addition of subcontractor
29 June 2005		Correction of address and reissue in new format
02 August 2006		Reissue due to change of company address and removal of subcontractor
21 February 2007		5 year certificate renewal
20 February 2012	7650496	Certificate renewal
06 February 2017	8621734	Certificate renewal

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