Certificate

Full Quality Assurance

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 under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.
For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **27 Feb 1997** Date: **20 Feb 2012**
Expiration Date: **26 Feb 2017**

Conditions of Approval
Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

raising standards worldwide™

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: +44 (0)845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL UK. A member of the BSI Group of Companies.

Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No.	**CE 01554**
Date:	**20 Feb 2012**
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	Guilford
	USA

Subcontractor	Service(s) supplied
Medical Market I.N.T. AB Sehlstedtsgatan 6 Stockholm Sweden 115 28	EU Representative

Certificate

History of Quality Assurance Certificate

Certificate No: **CE 01554**
Issue Date: **20 Feb 2012**
Issued to: **Bio-Med Devices**
Guildford
USA

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