By Royal Charter

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1997-02-27** Date: **2020-10-01** Expiry Date: **2022-02-26**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 01554

Issued To:

Bio-Med Devices
61 Soundview Road
Guilford
Connecticut
06437
USA

NBOG Code	Device Description	Intended Purpose
Class IIb		
MD 1102	Ventilator	For respiratory support of patients both in hospital and during transport.
MD 1102	Air-Oxygen blender	An accessory precision proportioning device (with one simple control) for mixing medical grade air and oxygen to any concentration from 21% to 100% oxygen, and delivering it to a ventilator (or other respiratory care device).
Class IIa		
MD 0101	Disposable breathing circuit.	N/A for Class IIa device.

First Issued: **1997-02-27** Date: **2020-10-01** Expiry Date: **2022-02-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 01554**
Date:	**2020-10-01**
Issued To:	**Bio-Med Devices** **61 Soundview Road** **Guilford** **Connecticut** **06437** **USA**

Subcontractor:	**Service(s) supplied**
Medicare Uitgeest BV Westerwerf 10 1911JA Uitgeest The Netherlands	**EU Representative**

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 01554**
Date: **2020-10-01**
Issued To: **Bio-Med Devices**
61 Soundview Road
Guilford
Connecticut
06437
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.
06 February 2017	8621734	Certificate renewal.
20 February 2019	7781673	Traceable to NB 0086.
Current	3282203	EU Rep Change from "Medical Market I.N.T. AB, Sehlstedtsgatan 6, Stockholm, 115 28, Sweden" to "Medicare Uitgeest BV, Westerwerf 10, 1911JA Uitgeest, The Netherlands." Device Table added.