EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 763237 R000

Manufacturer: Bio-Med Devices

Address:
61 Soundview Road
Guilford
Connecticut
06437
USA

Single Registration Number: Not Available

EU Authorised Representative: Medicare Uitgeest BV

Address:
Westerwerf 10
1911JA Uitgeest
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-11-09**

Current Issue Date: **2022-11-09**

Starting Validity Date: **2022-11-09**

Expiry Date: **2027-11-08**

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Device Schedule: Class III and Class IIb devices

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	Intended purpose
BMD Air / Oxygen Blender	The Air / Oxygen Blender is a medical device intended for use by qualified medical personnel to assist in the provision of intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The Air / Oxygen Blender can be used as a support device for ventilators intended for use in both invasive and non-invasive ventilation modes. The Air / Oxygen Blender can be wall-, pole-, or rail-mounted.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3597070	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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