



Bio-Med Devices Inc.  
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## ***DECLARATION OF CONFORMITY***

*We, Bio-Med Devices, Inc., declare our sole responsibility that*

*the product family, **Bio-Med Devices Air/Oxygen Blenders***

*(including the models: 2000, 2001, 2002, 2003, and 2004, with any suffix combinations, except those containing the letter "M". For suffixes with the letter "F", the flowmeters are not part of Bio-Med Devices' CE2797 certification), to which this declaration relates, is in conformity with the **Medical Devices***

*Regulation, that is, Regulation 2017/745 concerning medical devices (compliance achieved through Annex II), and Blender models as noted above are therefore entitled to bear the CE mark.*

*Furthermore, this product family is in compliance with the standard ISO 11195: 2018 "Gas Mixers for Medical Use - Stand-Alone Gas Mixers".*

*Finally, this product family incorporates no electronics, and is therefore not subject to the provisions of the EMC Directive, that is, Council Directive 2014/30/EU.*

*Basic UDI-DI: (00)813841022274*

*Device Classification: Class IIb (per Annex VIII Rules 2, 9, & 12)*

*Intended Purpose: The BMD blenders are precision air / oxygen blenders, intended for neonatal through adult human patients, in most medical environments from transport through intensive care (though not for homecare). They do not contact the patient, they are not invasive. The BMD blenders are durable medical equipment, which are in effect "reusable". The BMD blender is not shipped sterile.*

*This declaration applies to devices manufactured from serial number BX21500000 onwards.*

*Bio-Med Air/Oxygen Blender is manufactured in the sole facility at:*

*Bio-Med Devices, Inc. 61 Soundview Road Guilford, CT 06437 USA*

*Bio-Med Devices' Official Agent in Europe is: Medicare Uitgeest BV Westerwerf 10 1911JA Uitgeest Netherlands*

*Bio-Med Devices' Notified Body is: BSI (British Standards Institute) 2797 EC Certificate #: 763237*

*This declaration issued November 11, 2022 in Guilford, CT 06437 USA*

*Kenneth Close, Manager of Regulatory Affairs*