BIO-MED
DEVICES

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: 2001, 2002, 2003, 2004, and NeO2Blend, with any suffix combinations),

*to which this declaration relates, is in conformity with the **Medical Devices Directive**, that is, Council Directive 93/42/EEC concerning medical devices (compliance achieved through Annex II), and every Blender model is therefore entitled to bear the CE mark.*

*Furthermore, this product family is in compliance with **ISO 11195**: 1995 "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 89/336/EEC.

Device Classification: Class IIb (per Annex IX Rule 11)

This declaration applies to devices manufactured from serial number 006X06B onwards and to devices manufactured from serial number B1000000 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: Medical Market I.N.T. AB Sehlstedtsgatan 6 115 28 Stockholm Sweden

This declaration issued February 17, 2012
Guilford, CT 06437 USA

Kenneth Close
Manager of Regulatory Affairs