

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Bio-Med Devices
61 Soundview Road
Guilford
Connecticut
06437
USA

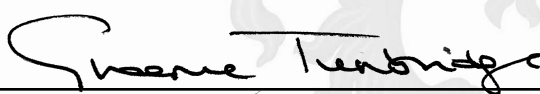
Holds Certificate Number:

FM 71213

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture, service and distribution of ventilators, oxygen blenders, monitors and breathing circuits.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2002-11-26

Latest Revision Date: 2025-07-01

Effective Date: 2025-07-08

Expiry Date: 2028-07-07

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