

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 No:

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.

Previous certificate expires on 07/07/2019
Re-certification audit ended 06/06/2019



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-11-26

Latest Revision Date: 2019-07-17

Effective Date: 2019-07-17

Expiry Date: 2022-07-07

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