



## 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.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-11-26 Latest Revision Date: 2018-12-06

Page: 1 of 1

...making excellence a habit."

Effective Date: 2019-01-01

Expiry Date: 2019-07-07



