



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Strata Medical Innovations, Inc.

3706 76th Street

Lubbock Texas 79423 USA

Holds Certificate No:

FM 650454

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

Design, development and manufacture of nitrous oxide gas delivery devices.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-08-09 Effective Date: 2019-01-01 Latest Revision Date: 2018-12-05 Expiry Date: 2019-08-08

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.