

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Carbon Medical Technologies, Inc.
1290 Hammond Road
St. Paul
Minnesota
55110
USA

Holds Certificate No:

FM 38359

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

The design and manufacture of Injectable Bulking Agents, Injection Needles, Implantable Tissue Markers and Tissue Marker Delivery Systems.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 1997-11-27

Latest Revision Date: 2021-01-07

Effective Date: 2020-11-06

Expiry Date: 2023-11-05



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