



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Specialty Manufacturing, Inc. 2210 Midland Road Saginaw Michigan 48603-3440 USA

Holds Certificate No:

FM 542984

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

The manufacture of quality silicone medical devices for the medical and pharmaceutical industries.

iames ada

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2008-10-07 Latest Revision Date: 2021-10-01





Effective Date: 2021-11-18 Expiry Date: 2024-11-17

Page: 1 of 1

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.