

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SterlingTech Inc.
dba/Sterling Medical Devices
17 Legion Place
Rochelle Park
New Jersey
07662
USA

Holds Certificate No:

FM 543438

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

Please see scope page.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2009-02-10

Latest Revision Date: 2018-01-29

Effective Date: 2018-02-10

Expiry Date: 2021-02-09

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Certificate No: **FM 543438**

Registered Scope:

Design, development and testing of microprocessor based medical devices including the following services:

- Product design, development and test
- Electronics design, development and test
- Software design, development and test
- Printed circuit board (PCB) design, development and test
- Mobile application design, development and test
- Verification testing at system and subsystem levels
- Design history file remediation
- Quality system consulting (QMS, submissions)
- Software tool validation
- Hazard Analysis
- Design risk assessment
- Software unit testing and code assessment



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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.