

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

SterlingTech Inc.  
dba/Sterling Medical Devices  
250 Moonachie Road  
Suite 400  
Moonachie  
New Jersey  
07074  
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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-02-10

Latest Revision Date: 2021-06-25

Effective Date: 2021-02-10

Expiry Date: 2024-02-09



Page: 1 of 2

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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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Page: 2 of 2

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](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.