



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally registered: 02/10/2009

Latest Issue: 01/21/2015

Expiry Date: 02/09/2018



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



Originally registered: 02/10/2009

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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.

Certificate No: **FM 543438**

Location	Registered Activities
SterlingTech Inc. dba/Sterling Medical Devices 17 Legion Place Rochelle Park New Jersey 07662 USA	Design, development and testing of microprocessor based medical devices including the following services: <ul style="list-style-type: none"><li>• Product design, development and test</li><li>• Electronics design, development and test</li><li>• Software design, development and test</li><li>• Printed circuit board (PCB) design, development and test</li><li>• Mobile application design, development and test</li><li>• Verification testing at system and subsystem levels</li><li>• Design history file remediation</li><li>• Quality system consulting (QMS, submissions)</li><li>• Software tool validation</li><li>• Hazard Analysis</li><li>• Design risk assessment</li><li>• Software unit testing and code assessment</li></ul>
Sterling Tech Inc., dba/ Sterling Medical Devices 218 Route 17 North Rochelle Park New Jersey 07662 USA	Design, development and testing of microprocessor based medical devices including the following services: <ul style="list-style-type: none"><li>• Product design, development and test</li><li>• Electronics design, development and test</li><li>• Software design, development and test</li><li>• Printed circuit board (PCB) design, development and test</li><li>• Mobile application design, development and test</li><li>• Verification testing at system and subsystem levels</li><li>• Design history file remediation</li><li>• Quality system consulting (QMS, submissions)</li><li>• Software tool validation</li><li>• Hazard Analysis</li><li>• Design risk assessment</li><li>• Software unit testing and code assessment</li></ul>

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