bsi.

By Royal Charter

# 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
Effective Date: 2018-02-10
Latest Revision Date: 2020-01-17
Expiry Date: 2021-02-09



...making excellence a habit.™

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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