

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Smart World LLC, dba Steri-Tek  
48225 Lakeview Blvd.,  
Fremont  
California  
94538  
USA

Holds Certificate Number:

**MD 648975**

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

The provision of contract electron beam irradiation sterilization service in accordance with EN ISO 11137-1:2015. The provision of irradiation for testing e-beam to customer requirements in accordance with EN ISO 11137-1:2015.

For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-07-15

Latest Revision Date: 2022-02-17

Effective Date: 2022-02-21

Expiry Date: 2025-02-20

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