

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:

Sterilization of medical devices by irradiation in accordance with ISO 11137-1:2006 +A1:2013 and EN ISO 11137-1:2015.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-07-15

Latest Revision Date: 2019-02-21

Effective Date: 2019-02-21

Expiry Date: 2022-02-20

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