

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

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-07-15

Latest Revision Date: 2025-02-10

Effective Date: 2025-02-21

Expiry Date: 2028-02-20

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Certificate No: MD 648975

Location

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

Steri-Tek LLC
1206 N Stemmons Freeway
Lewisville
Texas
75067
USA

Registered Activities

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.

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



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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