

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medisafe UK Limited  
Units 7 & 8  
Stortford Hall Industrial Park  
Dunmow Road  
Bishop's Stortford  
Hertfordshire  
CM23 5GZ  
United Kingdom

Facility ID Number: F000289

Holds Certificate No:

**MDSAP 694945**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brazil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of ultrasonic irrigation and ultrasonic washer/disinfector process equipment for medical purposes. Manufacture of enzymatic and detergent chemical products for use in transport and cleaning of medical instruments, instrument cleaning brushes and cleaning and sterilization assurance monitoring products.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-07-23

Effective Date: 2022-05-26

Expiry Date: 2025-04-20



BSI Group America Inc. is an MDSAP recognised auditing organization

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