

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

Holds Certificate Number:

MD 682107

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

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, and cleaning and sterilization assurance monitoring products.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-01-04

Latest Revision Date: 2025-03-18

Effective Date: 2025-04-21

Expiry Date: 2028-04-20



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