

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

KeyMed (Medical and Industrial  
Equipment) Ltd  
KeyMed House  
Stock Road  
Southend-on-Sea  
SS2 5QH  
United Kingdom

Facility ID Number: F000254

Holds Certificate No:

**MDSAP 689076**

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; Brasil - 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

The Design, Development and Manufacture of Endoscopic and Ultrasound equipment and accessories, including sterile products.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-26

Effective Date: 2021-03-25

Expiry Date: 2024-03-24



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 2

...making excellence a habit.™

Certificate No: **MDSAP 689076**

Location	Registered Activities
KeyMed (Medical and Industrial Equipment) Ltd KeyMed House Stock Road Southend-on-Sea SS2 5QH United Kingdom Facility ID Number: F000254	Administrative activities
KeyMed (Medical & Industrial Equipment) Ltd Medical Device Manufacture Centre Journeyman's Way Temple Farm Industrial Estate Southend on Sea Essex SS2 5TF United Kingdom Facility ID Number: F000254	The Design, Development and Manufacture of Endoscopic and Ultrasound equipment and accessories, including sterile products. This includes CNC machining; Metal fabrication; Powder coat painting process; and Screen printing.
KeyMed (Medical & Industrial Equipment) KeyMed KLM Building The Cordwainers Temple Farm Industrial Estate Southend-on-Sea Essex SS2 5RU United Kingdom Facility ID Number: F000254	The Design, Development and Manufacture of Endoscopic and Ultrasound equipment and accessories, including sterile products. This includes Management (regulatory affairs) & Warehouse activities.

Original Registration Date: 2018-10-26

Effective Date: 2021-03-25

Expiry Date: 2024-03-24

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.