

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

DUNS Number: 21-706-1423

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 [if design controls are part of the certification]; 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 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:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2018-10-26

Effective Date: 2019-03-15

Expiry date: 2021-03-24

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BSI Group America Inc. is an MDSAP authorized auditing organization

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Location	Registered Activities
KeyMed (Medical and Industrial Equipment) Ltd KeyMed House Stock Road Southend-on-Sea SS2 5QH United Kingdom DUNS Number: 21-706-1423	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 DUNS Number: 21-706-1423	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; Screen printing; and Warehousing processes carried out at KLM building SS2 5RU.



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This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

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