

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Key Surgical GmbH
Zum Windpark 1
Lensahn
23738
Germany

Holds Certificate Number:

MD 683647

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

Please see scope page.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-04-19

Latest Revision Date: 2020-04-16

Effective Date: 2019-05-03

Expiry Date: 2022-05-02

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Certificate No: **MD 683647**

Registered Scope:

The manufacture, packaging, storage, sales and distribution of packaging material for sterile medical devices, sterilisation containers and accessories and cannulas (sterile and non-sterile), biopsy valves (sterile and non-sterile), polyp traps (sterile), skin markers (sterile) and products for the maintenance, identification, protection and cleaning of surgical instruments.
Distribution of medical devices and associated products for central sterile supply departments, endoscopy and OR.

Herstellung, Verpackung, Lagerung, Verkauf und Vertrieb von Verpackungsmaterial für sterile Medizinprodukte, Sterilgutcontainer und Zubehör für Sterilgutcontainer und Kanülen (steril und unsteril), Biopsieventile (steril und unsteril), Polypenfälle (steril), Hautmarker (steril) und Produkten für Pflege, Identifikation, Schutz und Reinigung von chirurgischen Instrumenten.
Vertrieb von Medizinprodukten und zugehörigen Produkten für Zentralsterilisationsabteilungen, Endoskopie und OP.



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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate No: **MD 683647**

Location	Registered Activities
Key Surgical GmbH Zum Windpark 1 Lensahn 23738 Germany	<p>The manufacture, packaging and distribution of packaging material for sterile medical devices, sterilisation containers and accessories and cannulas (sterile and non-sterile), biopsy valves (sterile and non-sterile), polyp traps (sterile), skin markers (sterile) and products for the maintenance, identification, protection and cleaning of surgical instruments. Distribution of medical devices and associated products for central sterile supply departments, endoscopy and OR.</p> <p>Herstellung, Verpackung und Vertrieb von Verpackungsmaterial für sterile Medizinprodukte, Sterilgutcontainer und Zubehör für Sterilgutcontainer und Kanülen (steril und unsteril), Biopsieventile (steril und unsteril), Polypenfalle (steril), Hautmarker (steril) und Produkten für Pflege, Identifikation, Schutz und Reinigung von chirurgischen Instrumenten.</p> <p>Vertrieb von Medizinprodukten und zugehörigen Produkten für Zentralsterilisationsabteilungen, Endoskopie und OP.</p>
Key Surgical GmbH Stöckenhoop 6 Wentorf 21465 Germany	<p>Sales and storage of packaging material for sterile medical devices, sterilisation containers and accessories and cannulas (sterile and non-sterile), biopsy valves (sterile and non-sterile), polyp traps (sterile), skin markers (sterile) and products for the maintenance, identification, protection and cleaning of surgical instruments.</p> <p>Lagerung und Verkauf von Verpackungsmaterial für sterile Medizinprodukte, Sterilgutcontainer und Zubehör für Sterilgutcontainer und Kanülen (steril und unsteril), Biopsieventile (steril und unsteril), Polypenfalle (steril), Hautmarker (steril) und Produkten für Pflege, Identifikation, Schutz und Reinigung von chirurgischen Instrumenten.</p>

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