



By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

HOLOGIC INC
250 Campus Drive
Marlborough
Massachusetts
01752
USA

Holds Certificate Number:

FM 702779

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

The design, manufacture, distribution, and service of: sterile gynecological ablation systems with RF generators, sterile tissue removal systems for the minimally invasive visualization and removal of tissue, sterile hysteroscopic sealing devices, and sterile fluid management system, electrosurgical vessel sealing systems and surgical staple systems.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2006-07-03

Latest Revision Date: 2024-08-19

Effective Date: 2022-10-03

Expiry Date: 2025-10-02

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Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780

BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Americas Headquarters: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

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Location	Registered Activities
HOLOGIC INC 250 Campus Drive Marlborough Massachusetts 01752 USA	The design, distribution, and service of: gynecological sterile ablation systems with RF generators, sterile tissue removal systems for the minimally invasive visualization and removal of tissue, sterile hysteroscopic sealing devices, and sterile fluid management systems, electrosurgical vessel sealing systems and surgical staple systems.
Hologic Surgical Products Costa Rica, SRL 562 Parkway, Av. 0, Calle 0, Coyoil Free Zone El Coyoil Alajuela Costa Rica	The manufacturing of: gynecological sterile ablation handpieces, and accessories, sterile tissue removal handpieces and accessories, sterile hysteroscopic sealing devices, sterile fluid management handpieces and accessories.



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