

# 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 703385**

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

The design, manufacturing, distribution, and service of In-vitro diagnostic devices and related accessories for the collection, preservation, preparation, processing, imaging and evaluation of samples for the diagnosis of human diseases. The contract manufacturing, distribution and service of endometrial ablation systems with RF generators, tissue morcellation systems for the minimally invasive visualization and removal of tissue, fluid management systems, biopsy systems and control units for the minimally invasive visualization, x-ray imaging, and removal of tissue and radiofrequency surgical generators.

For and on behalf of BSI:

\_\_\_\_\_  
Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2005-12-05

Latest Revision Date: 2022-09-29

Effective Date: 2022-10-03

Expiry Date: 2025-10-02

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...making excellence a habit.™

Certificate No: FM 703385

Location	Registered Activities
Hologic, Inc. 250 Campus Drive Marlborough Massachusetts 01752 USA	The design and manufacture of In-vitro diagnostic devices and related accessories for the collection, preservation, preparation, processing, imaging and evaluation of samples for the diagnosis of human diseases.
Hologic, Inc. 4 Navigator Road Londonderry New Hampshire 03053 USA	The manufacture of In-vitro diagnostic devices and related accessories for the collection, preservation, preparation, processing, imaging and evaluation of samples for the diagnosis of human diseases.
Hologic Limited Partnership 14 Aegean Drive Unit A Methuen Massachusetts 01844 USA	The distribution of In-vitro diagnostic devices and related accessories for the collection, preservation, preparation, processing, imaging and evaluation of samples for the diagnosis of human diseases. The contract distribution of Gynecologic Surgical Solutions sterile and non-sterile products, Breast and Skeletal Health sterile and non-sterile products and Medical Aesthetics sterile and non-sterile products.
Hologic, Inc. 445 Simarano Drive Marlborough Massachusetts 01752 USA	The manufacture, distribution, service of In-vitro diagnostic devices and related accessories for the collection, preservation, preparation, processing, imaging and evaluation of samples for the diagnosis of human diseases. The contract manufacture and service of endometrial ablation systems with RF generators, tissue morcellation systems for the minimally invasive visualization and removal of tissue, fluid management systems, biopsy systems and control units for the minimally invasive visualization, x-ray imaging, and removal of tissue and radiofrequency surgical generators.

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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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