

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Foundation Medicine Inc.

150 2nd Street
Cambridge
Massachusetts
02141
USA

Holds Certificate Number:

FM 688017

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

Design, development, manufacture, distribution and delivery of laboratory companion diagnostics testing for genomic testing (oncology), pathology/histology IHC, H&E.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-11-29

Latest Revision Date: 2023-03-01

Effective Date: 2021-11-29

Expiry Date: 2024-11-28

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Certificate No: FM 688017

Location

Foundation Medicine Inc.
150 2nd Street
Cambridge
Massachusetts
02141
USA

Registered Activities

Design, development, manufacture, distribution and delivery of laboratory companion diagnostics testing for genomic testing (oncology), pathology/histology IHC, H&E.

Foundation Medicine GmbH
Nonnenwald 2
Building 433
Penzberg
82377
Germany

Delivery of laboratory diagnostics testing for genomics testing (oncology), pathology/histology IHC, H&E.



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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

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

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Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.