



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Genomic Health Inc 301 Penobscot Dr Redwood City California 94063 USA

Holds Certificate No:

FM 669470

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

Design, development, manufacture, distribution and management of outsourced processes, for specimen collection kits, reagents and associated software required to support treatment decisions for invasive breast cancer.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-10 Latest Revision Date: 2022-03-17

bsi.



Effective Date: 2021-10-10 Expiry Date: 2024-10-09

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

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