

Certificate of Registration

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

This is to certify that:

GRAIL LLC
1525 O'Brien Drive
Menlo Park
California
94025
USA

Holds Certificate Number: MD 784386

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

Design, development and manufacture of in vitro diagnostic tests, including reagents and software, for detection of cancer markers. Design, development, manufacture and distribution of in vitro diagnostic specimen collection kits for the transport of blood samples.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-11-09

Latest Revision Date: 2023-11-09

Effective Date: 2023-11-09

Expiry Date: 2026-11-08

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...making excellence a habit.™

Certificate No: MD 784386

Location	Registered Activities
GRAIL LLC 1525 O'Brien Drive Menlo Park California 94025 USA	Design, CAPA Management, Complaints Management, Warehouse (distribution).
GRAIL LLC 4001 E. Highway 545 Assembly Suite 1100 Durham North Carolina 27709 USA	Primary Manufacturing, Warehouse (distribution).



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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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