

Certificate of Registration

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

This is to certify that:

Hologic, Inc.
10210 Genetic Center Drive
San Diego
California
92121
USA

Holds Certificate Number:

MD 784806

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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-03-16

Latest Revision Date: 2024-04-11

Effective Date: 2024-05-14

Expiry Date: 2027-05-13



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...making excellence a habit.™

Certificate No: **MD 784806**

Registered Scope:

The design, development, and manufacture of in vitro diagnostic reagents, test kits and specimen collection kits used to aid in diagnosis and/or quantitation of viral load of sexually transmissible and infectious agents, and oncology markers.

The design, development, manufacture and service of in vitro diagnostic analyzers and software used to aid in the diagnosis of sexually transmissible and infectious agents, and oncology markers.

The design, development and manufacture of analyzers and software used for donor blood screening.

The design, development and manufacture of analyzers, lateral flow assays and specimen collection kits used as an aid to rapidly assess the risk of preterm delivery.



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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| Location | Registered Activities |
|--|---|
| Hologic, Inc. 10210 Genetic Center Drive San Diego California 92121 USA | Design, development, warehouse, manufacture of diagnostic reagents, test kits, specimen collection kits, lateral flow assays, analyzers and software. |
| Hologic, Inc. 6333 Sequence Dr. San Diego California 92121 USA | Design, development, warehouse, manufacture of in vitro diagnostic reagents and specimen collection kits, sales and servicing of instrumentation. |
| Hologic, Inc. 6060 Nancy Ridge Drive San Diego California 92121 USA | Warehouse, distribution. |
| Hologic, Inc. 9043 Siempre Viva Road San Diego California 92154 USA | Ambient temperature storage. |

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