



By Royal Charter

Certificate of Registration

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

This is to certify that:

Hologic Ltd.
Innovation House, Oaks Business Park
Crewe Road
Wythenshawe
Manchester
M23 9HZ
United Kingdom

Holds Certificate Number:

MD 797366

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

The manufacture of in vitro diagnostic reagents, test kits and specimen collection kits to aid in the diagnosis of sexually transmissible and infectious agents.
Certificate transfer from UL: Certificate Number 1516.230729.

For and on behalf of BSI:


Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2024-01-15

Latest Revision Date: 2024-01-15

Effective Date: 2024-01-15

Expiry Date: 2026-07-28

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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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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