

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Hardy Diagnostics
1430 W. McCoy Lane
Santa Maria
California
93455
USA

Holds Certificate Number:

FM 572526

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

Manufacture and design of microbiological culture media, instruments, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, bacterial and fungal detection and identification, microscopic examination, disease status, susceptibility tests, and detection of sexually transmissible agents.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2011-02-24

Effective Date: 2026-05-18

Latest Revision Date: 2026-03-18

Expiry Date: 2029-05-17



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Location	Registered Activities
Hardy Diagnostics 1430 W. McCoy Lane Santa Maria California 93455 USA	Manufacture and design of microbiological culture media, instruments, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, bacterial and fungal detection and identification, microscopic examination, disease status, susceptibility tests, and detection of sexually transmissible agents.
Hardy Diagnostics 1441 W. McCoy Lan Santa Maria California 93455 USA	Crown - Sales admin, document control, regulatory affairs, information systems, raw material overflow storage.
Hardy Diagnostics 1317 W. McCoy Lan Santa Maria California 93455 USA	Caleb - Raw material warehousing.
Hardy Diagnostics 1320 W. McCoy Lane Santa Maria California 93455 USA	Joshua - shipping and customer service.
Hardy Diagnostics 1360 W. McCoy Lane Santa Maria California 93455 USA	HEC - Marketing, Technical services, sales, manufacturing (DCM/Diluloks).
Hardy Diagnostics 429 South Pioneer Blvd Springboro Ohio 45066 USA	Manufacture of microbiological culture media, instruments, test kits and reagents, which are intended for the cultivation and identification of microorganisms and classified as in-vitro diagnostic medical devices. Distribution of a wide variety of in-vitro devices intended for such uses as prenatal screening, bacterial and fungal detection and identification, microscopic examination, disease status, susceptibility tests, and detection of sexually transmissible agents.

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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

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