

# 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 Medical Devices

Original Registration Date: 2011-02-24

Latest Revision Date: 2023-04-27

Effective Date: 2023-05-18

Expiry Date: 2026-05-17

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Certificate No: FM 572526

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 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](http://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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