

# 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 No:

**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:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-02-24

Latest Revision Date: 2020-09-09

Effective Date: 2020-05-18

Expiry Date: 2023-05-17

Page: 1 of 2



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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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Page: 2 of 2

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An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.