

# 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 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, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, and detection of sexually transmissible agents and pregnancy testing.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2011-02-24

Latest Revision Date: 2018-12-20

Effective Date: 2017-05-18

Expiry Date: 2020-05-17

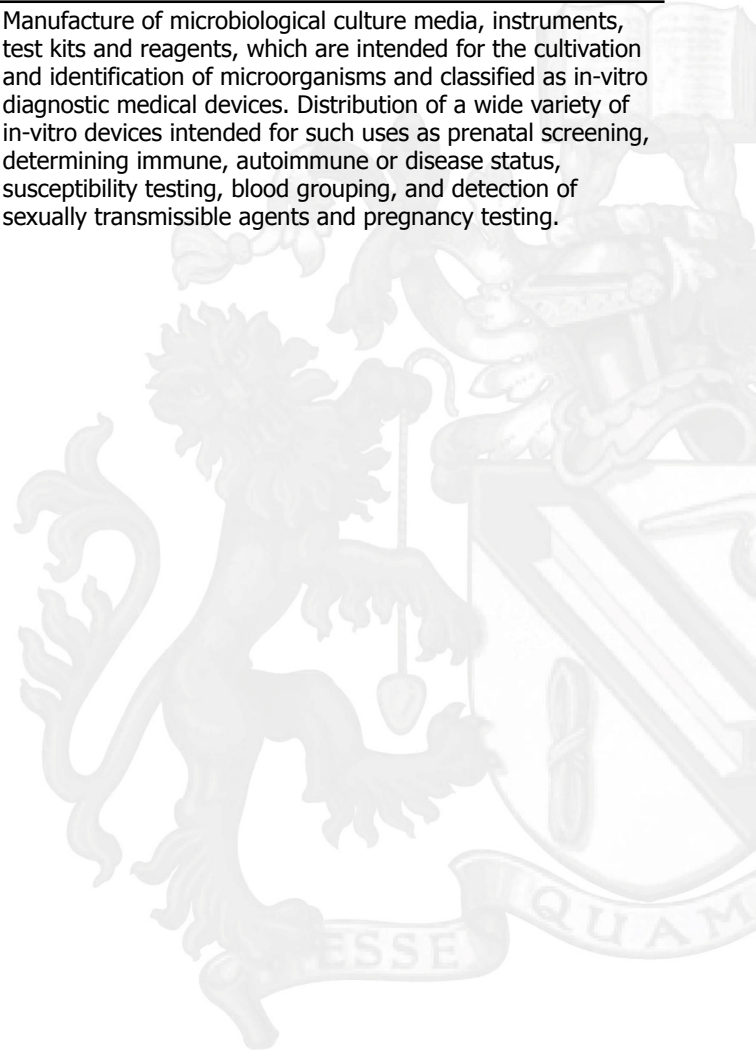
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...making excellence a habit.™

Certificate No: **FM 572526**

| Location   | Registered Activities  |
|--|--|
| Hardy Diagnostics<br>1430 W. McCoy Lane<br>Santa Maria<br>California<br>93455<br>USA | Manufacture and design of microbiological culture media, 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, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, detection of sexually transmissible agents and pregnancy testing.       |
| Hardy Diagnostics<br>429 South Pioneer Blvd<br>Springboro<br>Ohio<br>45066<br>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, determining immune, autoimmune or disease status, susceptibility testing, blood grouping, and detection of sexually transmissible agents and pregnancy testing. |



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.