bsi.

By Royal Charter

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
Effective Date: 2017-05-18
Latest Revision Date: 2018-12-20
Expiry Date: 2020-05-17

...making excellence a habit.™

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

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