

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

BioSure (UK) Limited
Unit 59 Hillgrove Business Park
Nazeing Road
Essex
EN9 2HB
United Kingdom

Holds Certificate Number:

MD 614350

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

The design, manufacturing, packaging and distribution of in-vitro diagnostic kits for self-test and professional use diagnosis of infectious disease. The distribution of medical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-04-13

Latest Revision Date: 2021-04-09

Effective Date: 2021-04-13

Expiry Date: 2021-10-12

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