

Certificate of Registration

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

This is to certify that:

Abionic SA
Biopôle, sect. Esplanade SE-B
Route de la Corniche 5
CH-1066 Epalinges
Switzerland

Holds Certificate Number:

MD 709346

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

Design, development, manufacturing and sales of in vitro diagnostic kits, instrumentation and software for the detection of blood proteins based on biosensor technology.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-07-10

Latest Revision Date: 2020-01-30

Effective Date: 2020-04-01

Expiry Date: 2023-03-31

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