

Certificate of Registration

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

This is to certify that:

Alsachim SAS
160 rue Tobias Stimmer
Illkirch Graffenstaden
67400
France

Holds Certificate Number:

MD 684937

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 and development, manufacture and sales of in vitro diagnostic kits for therapeutic drug monitoring of immunosuppressant drugs in whole blood by LC-MS/MS.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-07-25

Latest Revision Date: 2018-07-25

Effective Date: 2018-07-25

Expiry Date: 2021-07-24

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