



## 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-07-25

Latest Revision Date: 2022-01-24

Effective Date: 2021-07-25

Expiry Date: 2024-07-24

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...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Certificate No: MD 684937

Location Registered Activities

Alsachim SAS 160 rue Tobias Stimmer Illkirch Graffenstaden 67400 Registration address.

Alsachim SAS 70 rue Tobias Stimmer Illkirch Graffenstaden 67400

France

France

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.



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