

# 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:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-07-25

Latest Revision Date: 2024-07-04

Effective Date: 2024-07-25

Expiry Date: 2027-07-24

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Certificate No: MD 684937

Location

Alsachim SAS  
160 rue Tobias Stimmer  
Illkirch Graffenstaden  
67400  
France

Alsachim SAS  
70 rue Tobias Stimmer  
Illkirch Graffenstaden  
67400  
France

Registered Activities

Registration address.

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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