

Certificate of Registration

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

This is to certify that:

Bloom Diagnostics AG
Susenbergstrasse 185
8044 Zürich
Switzerland

Holds Certificate Number:

MD 693334

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, development, manufacture and distribution of IVD self-tests, associated software and instruments for the quantitative determination of biomarkers.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-03-19

Latest Revision Date: 2020-03-19

Effective Date: 2020-03-19

Expiry Date: 2023-03-18

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Certificate No: **MD 693334**

Location

Bloom Diagnostics AG
Susenbergstrasse 185
8044 Zürich
Switzerland

Bloom Diagnostics GmbH
Borseplatz 6/2/19-20
1010 Vienna
Austria

Registered Activities

Manufacture and distribution of IVD self-tests.

Sales and distribution, design and development of software.



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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 [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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