

Certificate of Registration

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

This is to certify that:

Biocartis NV
Generaal De Wittelaan 11B
2800 Mechelen
Belgium

Holds Certificate Number:

MD 731061

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, manufacture, installation, distribution and service of molecular based in-vitro diagnostic systems, including instruments, reagents and software used in the field of oncology and infectious diseases.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-10-05

Latest Revision Date: 2024-11-20

Effective Date: 2024-02-03

Expiry Date: 2027-02-02

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Certificate No: MD 731061

Location	Registered Activities
Biocartis NV Generaal De Wittelaan 11B 2800 Mechelen Belgium	Design, development, manufacture, installation, distribution and service of molecular based in-vitro diagnostic systems, including instruments, reagents and software used in the field of oncology and infectious diseases.
Biocartis US Inc. 2 Pierce Place Suite 1510 Itasca Illinois 60143-1203 USA	Distribution, installation and service.



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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

Information and Contact:

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
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