



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 064137 0024 Rev. 06

Holder of Certificate:



Bruker Daltonics GmbH & Co. KG

Fahrenheitstrasse 4
28359 Bremen
GERMANY

Certification Mark:



Scope of Certificate:

Design and development and production of in vitro diagnostic reagents and reagent products, related accessories and control materials, as well as instruments and software for Microbiology and Infectious Immunology. Warehousing and distribution of in vitro diagnostic reagents and reagent products, related accessories and control materials, as well as sterile and non-sterile consumables for Immunochemistry, Hematology, Microbiology, Infectious Immunology and Genetic Testing.

Warehousing, distribution, installation and service of in vitro diagnostic instruments, sample processing systems, related accessories and supplies, as well as software for hematology, histology, cytology and general diagnostic use.

The provision of monoclonal antibodies and recombinant proteins for in vitro diagnostic reagents, reagent products and control materials for Immunochemistry, Microbiology and Infectious Immunology.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 064137 0024 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_064137_0024_Rev_06)

Report No.:

713352719

Valid from:

2025-06-23

Valid until:

2028-06-22

Date, 2025-05-06

Christoph Dicks

Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Bruker UK Limited**
5 Robroyston Oval, Nova Business Park, Glasgow, G33 1AP,
UNITED KINGDOM

Design and development and production of in vitro diagnostic reagents, reagent products and control materials for Microbiology and Infectious Immunology.
Distribution of in vitro diagnostic reagents and reagent products, related accessories and control materials for Immunochemistry, Microbiology and Infectious Immunology.

Bruker Daltonics GmbH & Co. KG
Fahrenheitstrasse 4, 28359 Bremen, GERMANY

Design and development and production of in vitro diagnostic reagents and reagent products, related accessories and control materials, as well as instruments and software for Microbiology and Infectious Immunology.
Warehousing and distribution of in vitro diagnostic reagents and reagent products, related accessories and control materials, as well as sterile and non-sterile consumables for Immunochemistry, Hematology, Microbiology, Infectious Immunology and Genetic Testing.
Warehousing, distribution, installation and service of in vitro diagnostic instruments, sample processing systems, related accessories and supplies, as well as software for hematology, histology, cytology and general diagnostic use.

InVivo BioTech Services GmbH
Oranienstrasse 24, 10999 Berlin, GERMANY

Design and development and production of in vitro diagnostic reagents and reagent products and control materials for Immunochemistry, Microbiology and Infectious Immunology.

InVivo BioTech Services GmbH
Neuendorfstrasse 24a, 16761 Hennigsdorf, GERMANY

Design and development and production of in vitro diagnostic reagents, reagent products and control materials for Immunochemistry, Microbiology and Infectious Immunology.
The provision of monoclonal antibodies and recombinant proteins for in vitro diagnostic reagents, reagent products and control materials for Immunochemistry, Microbiology and Infectious Immunology.



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MERLIN Gesellschaft für mikrobiologische Diagnostika mbH

Kleinstrasse 14, 53332 Bornheim, GERMANY

Design and development and production of in vitro diagnostic reagents, reagent products, related accessories and control materials, as well as instruments for Microbiology and Infectious Immunology.

Installation, service and distribution of in vitro diagnostic instruments for Microbiology and Infectious Immunology.

Distribution of in vitro diagnostic reagents and reagent products, related accessories and control materials for Microbiology and Infectious Immunology.

Bruker Daltonics GmbH & Co. KG

Borgwardstrasse 11, 28279 Bremen, GERMANY

Production of in vitro diagnostic instruments and software for Microbiology and Infectious Immunology.

Distribution, installation and service of in vitro diagnostic instruments and software for Microbiology and Infectious Immunology.

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