



# Certificate

No. Q5 064137 0024 Rev. 04

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, control materials, instruments and software for Immunochemistry, Microbiology and Infectious Immunology. Installation, servicing and distribution of in vitro diagnostic instruments and software 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. The provision of monoclonal antibodies and recombinant proteins for in vitro diagnostic reagents and 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 and certification regulation of 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. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5 064137 0024 Rev. 04)

Report No.: 713239292

Valid from: 2022-06-23

Valid until: 2025-06-22

Date, 2022-06-23

Christoph Dicks

Head of Certification/Notified Body

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**Applied Standard(s):**

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**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, control materials, instruments and software for Microbiology and Infectious Immunology.

Installation, maintenance servicing and distribution of in vitro diagnostic instruments and software for Microbiology and Infectious Immunology.

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

**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 and reagent products and control materials for Immunochemistry, Microbiology and Infectious Immunology.

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

