



Certificate

No. Q5 064137 0024 Rev. 03

Holder of Certificate: **Bruker Daltonics GmbH & Co. KG**



Fahrenheitstrasse 4
28359 Bremen
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, manufacturing, sales, distribution, installation and servicing of instruments, systems and reagents for in vitro diagnostic use**

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. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_064137_0024_Rev._03)

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Valid from: 2021-05-28

Valid until: 2022-06-30

Date, 2021-05-28

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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, production and distribution of in-vitro
diagnostics

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

Design and Development, Manufacturing, Sales, Installation and
Servicing of instruments, Systems and Reagents for in-vitro
Diagnostic Use

InVivo BioTech Services GmbH
Oranienstrasse 24, 10999 Berlin, GERMANY

Design and Development, manufacturing and sales of monoclonal
antibodies, recombinant proteins and diagnostic kits and single
reagents

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

Design and Development, manufacturing of monoclonal
antibodies, recombinant proteins and diagnostic kits and single
reagents

MERLIN Diagnostika GmbH
Kleinstrasse 14, 53332 Bornheim, GERMANY

Design and Development, manufacturing and sales of
microbiological diagnostic systems for in-vitro diagnostic use

Bruker Daltonics GmbH & Co. KG
Borgwardstrasse 11, 28279 Bremen, GERMANY

Manufacturing and storage of instruments

Parameters: ./.