



Certificate

No. Q5 089706 0001 Rev. 02

Holder of Certificate: **Kibion GmbH**
Haferwende 31
28357 Bremen
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, production, distribution, installation and service of *in vitro* diagnostic instruments and specimen receptacles for the detection of infectious agents and disorders in the field of breath test diagnostics**

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 089706 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_089706_0001_Rev_02)

Report No.: 713331202

Valid from: 2024-08-02
Valid until: 2027-08-01

Date, 2024-07-17

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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): **Kibion GmbH**
Haferwende 31, 28357 Bremen, GERMANY

Production, distribution, installation and service of *in vitro*
diagnostic instruments and specimen receptacles for the detection
of infectious agents and disorders in the field of breath test
diagnostics

Laboratoires Mayoly Spindler SAS
Mayoly Diagnostics Business Unit
3 place Renault, 92500 Rueil-Malmaison, FRANCE

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in vitro diagnostic instruments and specimen receptacles for the
detection of infectious agents and disorders in the field of breath
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