



Product Service

Certificate

No. Q5 077568 0010 Rev. 00

Holder of Certificate: **Analyticon Biotechnologies GmbH**
Am Mühlberg 10
35104 Lichtenfels
GERMANY

Certification Mark:



Scope of Certificate: **Development, production and distribution of in-vitro diagnostics reagents from the field of urine diagnostics for professional and near-patient applications.**
Development, production, distribution, service and installation of in-vitro-diagnostic analyzers and software from the field of urine diagnostics.
Distribution of in-vitro diagnostic devices from the field of hematology.
Distribution and service of in-vitro-diagnostic analyzers from the field of hematology.

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 077568 0010 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_077568_0010_Rev_00)

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Valid from: 2025-11-25

Valid until: 2028-01-10

Date, 2025-11-25

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): **Analyticon Biotechnologies GmbH**
Am Mühlenberg 10, 35104 Lichtenfels, GERMANY

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Development, production, distribution, service and installation of in-vitro-diagnostic analyzers and software from the field of urine diagnostics.
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Analyticon Biotechnologies GmbH
Am Teichsberg 10a, 35104 Lichtenfels, GERMANY

Reception, shipping and storage of raw materials, semi-finished goods, finished goods and analysers from the fields of urine diagnostics and hematology.

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