



# Certificate

No. Q5 057136 0012 Rev. 02

**Holder of Certificate:** **Chromsystems  
Instruments & Chemicals GmbH**  
Am Haag 12  
82166 Gräfelfing  
GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for HPLC and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.**

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 057136 0012 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 057136 0012 Rev. 02)

**Report No.:** 713336612, 713336612\_CN

**Valid from:** 2024-08-22

**Valid until:** 2027-08-21

**Date,** 2024-08-09



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):** **Chromsystems Instruments & Chemicals GmbH**  
Am Haag 12, 82166 Gräfelfing, GERMANY

Design and development, production and distribution of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for HPLC and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.

**Chromsystems Instruments & Chemicals GmbH**  
Lochamer Schlag 11 a, 82166 Gräfelfing, GERMANY

Warehousing of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for HPLC and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.

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Order handling of in vitro diagnostic medical devices [calibrators, controls, reagents and components used for HPLC and mass spectrometry], used in the diagnosis and management of cancer, disease status, drug abuse, endocrine disorders, protein metabolism, blood analytes, vitamin profiling, osteoporosis diagnosis, occupational medicine, oxidative stress, biomarker of alcohol abuse and for therapeutic drug monitoring.

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