



America

# CERTIFICATE

No. QS6 057136 0013 Rev. 03

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits used in the Diagnosis and Management of Cancer, Disease Status, Drug of Abuse, Endocrine Disorders, Protein Metabolism, Blood Analytes, Vitamin Profiling, Osteoporosis Diagnosis, Occupational Medicine, Oxidative Stress, Biomarker of Alcohol of Abuse and for Therapeutic Drug Monitoring**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, USA FDA.  
See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_057136\\_0013\\_Rev\\_03](http://www.tuvsud.com/ps-cert?q=cert:QS6_057136_0013_Rev_03)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F001658**  
**Report No.:** **713336612**  
**Effective Date:** **2024-08-19**  
**Expiry Date:** **2024-12-10**

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Date of Issue: 2024-08-20

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Director, US Certification Body, MHS



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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices  
- RDC ANVISA n. 551/2021  
- RDC ANVISA n. 67/2009 - Vigilance

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Facility(ies):

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

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

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**Chromsystems Instruments & Chemicals**

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**Chromsystems Instruments & Chemicals**

Lochhamer Schlag 11a, 82166 Gräfelfing, GERMANY

Warehousing of In-Vitro Diagnostic Medical Devices for HPLC and Mass Spectrometry  
REPs Facility ID: F001658

**Chromsystems Instruments & Chemicals**

Lochhamer Schlag 11, 82166 Gräfelfing, GERMANY

Order Handling of In-Vitro Diagnostic Medical Devices for HPLC and Mass Spectrometry  
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