



America

CERTIFICATE

No. QS6 057136 0013 Rev. 01

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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001658**

Effective Date: **2021-12-24**

Expiry Date: **2024-12-10**

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Date of Issue: 2021-12-28

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



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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. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

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):

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