MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 057136 0013 Rev. 00

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

Certification Mark:

Scope of Certificate: **The 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, Drugs of Abuse, Endocrine Disorders, Protein Metabolism, Blood Analytes, Vitamin Profiling, Osteoporosis Diagnosis, Occupational Medicine, Oxidative Stress, Biomarker of Alcohol of Abuse, and 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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **32-871-2260**

Effective Date: **2018-12-11**

Expiry Date: **2021-12-10**

Date of Issue: 2018-12-17

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies): Chromsystems Instruments & Chemicals GmbH
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