MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 101533 0001 Rev. 00

Certificate Holder:

Stanbio Laboratory, L.P.
ata Stanbio Laboratory
ata Separation Technology, Inc
1261 North Main Street
Boerne TX 78006
USA

Certification Mark:

TÜV SÜD ISO 13485

Scope of Certificate:

Design, Development, Manufacture, Packaging, Re-Packaging, Installation, Service and Distribution of In-Vitro Diagnostic Analyzers, In-Vitro Diagnostic Reagents, and In-Vitro Diagnostic Test Kits used in the Diagnosis, Management, and Detection of Blood Analytes, Blood Gases, Cardiac Markers, Disease Status, Pregnancy Testing, Sexually Transmissible Agents, Therapeutic Drug Monitoring including near Patient/Point of Care In-Vitro Diagnostic Devices

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: **07-978-9999**

Effective Date: **2019-08-09**

Expiry Date: **2022-08-08**

Date of Issue: 2019-10-03

Dawn Tibodeau

(Dawn M. Tibodeau)
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):
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Facility Scopes:
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