ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 101533 0001 Rev. 03

Certificate Holder:

Stanbio Laboratory, L.P.
also trading as Stanbio Laboratory,
Separation Technology, Inc,
and EKF Diagnostics, Inc
1261 North Main Street
Boerne TX 78006
USA

Certification Mark:

Scope of Certificate:

Design, Development, Manufacture, Service and Distribution of In-Vitro Diagnostics 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. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:QS6 101533 0001 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F004419**
Report No.: **72185268**
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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

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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): Stanbio Laboratory, L.P. also trading as Stanbio Laboratory, Separation Technology, Inc, and EKF Diagnostics, Inc
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Facility Scopes: Design, Development, Manufacture, Packaging, Re-Packaging, Service and Distribution of In-Vitro Diagnostics 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
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