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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# CERTIFICATE

## No. QS6 101533 0001 Rev. 02

**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, 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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F004419**

**Effective Date:** **2022-08-09**

**Expiry Date:** **2025-08-08**


**Date of Issue:** 2022-08-04

( Renee Walker )
Manager, US Certification Body,
Medical and Health Services

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# C E R T I F I C A T E

## No. QS6 101533 0001 Rev. 02

**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):**

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

Stanbio Labratory L.P. also trading as Stanbio Labratory, Separation Technology, Inc And EKF Diagnostics, Inc
179 Enterprise Parkway, Boerne TX 78006, USA

Stanbio Laboratory L.P. also trading as Stanbio Laboratory, Separation Technology, Inc. and EKF Diagnostics, Inc.
11803 Starcrest Drive, San Antonio TX 78247, USA


**Date of Issue:** 2022-08-04

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# C E R T I F I C A T E

## No. QS6 101533 0001 Rev. 02

**Facility Scopes:**

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

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
REPs Facility ID: F004419

**Stanbio Labratory L.P. also trading as Stanbio Labratory, Separation Technology, Inc, And EKF Diagnostics, Inc**
179 Enterprise Parkway, Boerne TX 78006, USA

Packaging, Quality Control, and Warehousing of In-Vitro Diagnostic Reagents and Test Kits
REPs Facility ID: F004419

**Stanbio Laboratory L.P. also trading as Stanbio Laboratory, Separation Technology, Inc. and EKF Diagnostics, Inc.**
11803 Starcrest Drive, San Antonio TX 78247, USA

Packaging, Quality Control, and Warehousing of In-Vitro Diagnostic Reagents and Test Kits
REPs Facility ID: F004419


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