



America

CERTIFICATE

No. QS2 101533 0002 Rev. 00

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: See Page 2 for Overall Scope Statement

Standard: ISO 13485:2016

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: 72180785

Effective Date: 2022-10-12

Expiry Date: 2025-08-08

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Date of Issue: 2022-10-27

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



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Overall Scope Statement:

Design, Development, Manufacture, Packaging, Re-Packaging, Installation, Service, Sales, and Distribution of In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Analyzers, 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;

Manufacture of Enzyme Intermediates used in In-Vitro Diagnostics for the Detection of Blood and Urine Analytes;

Contract Manufacture of In-Vitro Diagnostics used in Therapeutic Drug Monitoring;

Contract Manufacture of Reagents, Accessories, and Components of In-Vitro Diagnostics and Health Care Related Products;

Contract Manufacture of In-Vitro Diagnostics used in the Collection and Transport of Human Samples for Laboratory Testing;

Contract Manufacture of In-Vitro Diagnostics, Reagents and Kits of In-Vitro Diagnostics and Health Care Related Products

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

Facility Scopes: Design, Development, Manufacture, Packaging, Re-Packaging, Installation, Service, Sales, and Distribution of Hemoglobin Reagent and Analyzer, Chemistry Reagents and Analyzer, 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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Facility(ies): Stanbio Laboratory, L.P. also trading as Stanbio Laboratory, Separation Technology, Inc And EKF Diagnostics, Inc
179 Enterprise Parkway, Boerne TX 78006, USA

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

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

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

Facility(ies): EKF Life Sciences
1814 Leer Drive, Elkhart IN 46514, USA

Facility Scopes: Contract Manufacture of In-Vitro Diagnostics used in Therapeutic Drug Monitoring;
Contract Manufacture of Reagents, Accessories, and Components of In-Vitro Diagnostics and Health Care Related Products;
Manufacture of Enzyme Intermediates Used in In-Vitro Diagnostics for the Detection of Blood and Urine Analytes

Facility(ies): EKF Diagnostics Holdings plc
Avon House, 19 Stanwell Road, Penarth, Cardiff [Caerdydd GB, CF64 2EZ, UNITED KINGDOM

Facility Scopes: Contract Manufacture of In-Vitro Diagnostics used in the Collection and Transport of Human Samples for Laboratory Testing;
Contract Manufacture of In-Vitro Diagnostics, Reagents for In-Vitro Diagnostics and Health Care Related Products

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Facility(ies):

EKF Diagnostics Holdings plc

Llandough Trading Estate Unit 20, 21, 22, Penarth Road, Cardiff,
CF11 8RR, UNITED KINGDOM

Facility Scopes:

Contract Manufacture of In-Vitro Diagnostics used in the
Collection and Transport of Human Samples for Laboratory
Testing;

Contract Manufacture of In-Vitro Diagnostics, Reagents for
In-Vitro Diagnostics and Health Care Related Products

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