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

SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS2 101533 0002 Rev. 05

Certificate Holder: **EKF Diagnostics, Inc, also trading as Stanbio Laboratory, LLC, Stanbio Laboratory, Separation Technology, Inc, and EKF Life Sciences**
1261 North Main Street
Boerne TX 78006-3014
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.: **721002181**

Effective Date: **2025-08-09**

Expiry Date: **2028-08-08**

Date of Issue: 2025-06-10

(Renee Walker)
Director, US Certification Body, MHS

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TÜV SÜD America

CERTIFICATE

No. QS2 101533 0002 Rev. 05

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

Facility(ies):

EKF Diagnostics, Inc, also trading as Stanbio Laboratory, LLC Stanbio Laboratory, Separation Technology, Inc, EKF Life Sciences
1261 North Main Street, Boerne TX 78006-3014, 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

Date of Issue: 2025-06-10

(Renee Walker)
Director, US Certification Body, MHS

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America

C E R T I F I C A T E

No. QS2 101533 0002 Rev. 05

Facility(ies):

EKF Life Sciences
6879 Enterprise Drive, Suite 500, South Bend IN 46628, USA

Facility Scopes:

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

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

Date of Issue: 2025-06-10

(Renee Walker)
Director, US Certification Body, MHS