



America

# CERTIFICATE

No. QS2 103419 0001 Rev. 00

**Certificate Holder:** EKF Life Sciences  
1814 Leer Drive  
Elkhart IN 46514  
USA

**Certification Mark:**



**Scope of Certificate:** Manufacture of In-Vitro Diagnostics used in  
Therapeutic Drug Monitoring and the Manufacture  
of Enzyme Intermediates used in In-Vitro  
Diagnostics for the Detection of Blood Analytes

**Standard(s):** 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.:** 72148027

**Effective Date:** 2019-10-22

**Expiry Date:** 2022-10-21

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( Dawn M. Tibodeau )  
Manager, Certification Body MHS

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