



America

# CERTIFICATE

No. QS2 18 04 61256 006

**Certificate Holder:** ARKRAY Factory USA, Inc.  
5182 West 76th Street  
Edina MN 55439  
USA

**Certification Mark:**



**Scope of Certificate:** The Design and Development of In-Vitro Diagnostic Medical Device Software; The Manufacture, Distribution, Installation and Service of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Analyzers-Software, Urine Analysis, Blood Analysis, and Blood Glucose Monitoring Used in the Management of Disease Status, Including Home Use and Near Patient In-Vitro Diagnostic Devices; The Distribution of Lancets, Lancing Devices, Safety Syringes, Pen Needles, and Sharps Containers

**Standard(s):** ISO 13485:2003

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.:** M1453

**Effective Date:** 2018-04-09

**Expiry Date:** 2019-02-28

Manuel Bradaric  
MHS Certification Manager



Page 1 of 1

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TÜV®

