



America

CERTIFICATE

No. QS1 17 02 61256 005

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, Installation, Service and Distribution of In-Vitro Diagnostic Medical Devices, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Analyzers-Software, Lancets, Lancing Devices, Insulin Safety Syringes, Pen Needles, and Sharps Containers Used in the Management of Disease Status, Urine Analysis and Blood Glucose Monitoring Including Home Use and Near Patient In-Vitro Diagnostic Devices

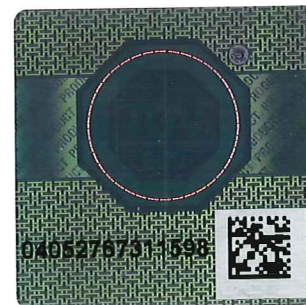
Standard(s): ISO 13485:2003

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.

TÜV SÜD America Inc. is a Health Canada CMDCAS Recognized Registrar.

Report No.: M1453
Effective Date: 2017-02-01
Expiry Date: 2018-12-31

Gary Minks
Vice President, Regulatory Affairs



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