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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

TÜV SÜD America Inc.
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USA

SCC Accredited CB-MS OCSM Accrédité CCN