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

SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS2 061256 0007 Rev. 00

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, and In-Vitro Diagnostic Analyzers-Software used to Analyze Bodily Fluids to Monitor and Manage Disease Status, including Home Use and Near Patient In-Vitro Diagnostic Devices; The Distribution of Lancets, Lancing Devices, Syringes, Pen Needles, and Sharps Containers**

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.: **72141289**

Effective Date: **2019-01-21**

Expiry Date: **2022-01-20**

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(Arie Henkin)

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