



America

# CERTIFICATE

No. QS2 061256 0007 Rev. 01

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development of In-Vitro Diagnostic Medical Device Software; 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; Distribution of Lancets, Lancing Devices, Syringes, Pen Needles, Sharps Containers, and Swallowing Aid Gel**

**Standard:** **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.:** **72151893**

**Effective Date:** **2020-10-06**

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

Page 1 of 1

**Date of Issue:** 2020-10-15

( Tina Israel )  
Manager, US Certification Body,  
Medical and Health Services