

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ARKRAY Factory USA, Inc.

Main Site: 5182 West 76th Street

Edina, MN 55439 USA

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

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.

Organization was certified by another Certification Body before 06/25/2021

Certificate Number:

0115074

Date of Certification Decision:

2021-06-24

Issuing Date:

2021-06-25

Valid Until:

2022-01-20



The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

intertek

Calin Moldovean
President

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