



Certificate

No. Q5 027591 0044 Rev. 04

Holder of Certificate: **ARKRAY Factory, Inc.**
1480 Koji, Konan-cho
Koka-shi, Shiga 520-3306
JAPAN

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, Sales and Servicing of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate In-Vitro Diagnostic Devices: In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 027591 0044 Rev. 04

Report No.: JN1660055B

Valid from: 2022-04-06

Valid until: 2024-11-30

Date, 2022-04-06



Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 027591 0044 Rev. 04

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ARKRAY Factory, Inc.
1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

Production and Distribution of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System

ARKRAY, Inc.

Yousuien-nai, 59 Gansuin-cho, Kamigyo-ku, Kyoto 602-0008, JAPAN

Design and Development of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System

ARKRAY Global Business, Inc.

Yousuien-nai, 59 Gansuin-cho, Kamigyo-ku, Kyoto 602-0008, JAPAN

Sales of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System

ARKRAY Marketing, Inc.

Taiga Bldg. 4F, 1-20-20 Yotsuya, Shinjuku-ku, Tokyo 160-0004, JAPAN

Sales of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System

Certificate

No. Q5 027591 0044 Rev. 04

ARKRAY Infinity, Inc.
1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

Servicing of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose, System for Self-testing of Blood Lactate

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing, Genetic Testing System

ARKRAY Industry, Inc.
Lot 22 Phase 1A, First Philippine Industrial Park, Brgy. Sta. Anastacia, Sto. Tomas, Batangas 4234, PHILIPPINES

Production and Distribution of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing

ARKRAY Factory Pinghu, Inc.
Building 8 No. 988, Xinxing No. 2 Road of PETDZ, Zhejiang 314200, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits, In-Vitro Diagnostic Analyzers used in Urinalysis, Hematological Testing, Biochemical Testing and Immunological Testing

ARKRAY Industry West, Inc.
Main Avenue Cor. 3rd Street, Cavite Economic Zone, Rosario, Cavite 4106, PHILIPPINES

Production and Distribution of Diagnostic Devices (IVD), Lancing Device, System for Self-testing of Blood Glucose

In-Vitro Diagnostic Devices:

In-Vitro Diagnostic Reagents, In-Vitro Diagnostic Test Kits

-/-