



# Certificate

No. Q5 027591 0044 Rev. 05

**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, Installation 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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 027591 0044 Rev. 05)

**Report No.:** **JN1854978**

**Valid from:** **2023-02-28**

**Valid until:** **2024-11-30**

**Date,** **2023-02-28**



Christoph Dicks

Head of Certification/Notified Body

# Certificate

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## 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. 5F, 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

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

Installation 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

**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

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