



Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00



Product Service

# Certificate

No. Q5 027591 0044 Rev. 07

**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 of In vitro diagnostic reagents and reagent products, calibrators and control materials for Clinical Chemistry, Immunochemistry, Infectious Immunology, Genetic Testing and Lancing Device.**

**Design and Development, Production, Distribution, Sales, Installation and Servicing of In vitro diagnostic instruments for Clinical Chemistry, Immunochemistry and Nucleic Acid Testing.**

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, Certification, Validation and Verification Regulations 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. 07](http://www.tuvsud.com/ps-cert?q=cert:Q5 027591 0044 Rev. 07)

**Report No.:** JV200350010747\_CN

**Valid from:** 2025-11-27

**Valid until:** 2027-11-30

**Date,** 2025-11-27

Christoph Dicks  
Head of Certification/Notified Body



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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **ARKRAY Factory, Inc.**  
1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN  
  
Production and Distribution of In vitro diagnostic reagents and reagent products, calibrators and control materials for Clinical Chemistry, Immunochemistry, Infectious Immunology, Genetic Testing and Lancing Device.  
Production and Distribution of In vitro diagnostic instruments for Clinical Chemistry, Immunochemistry and Nucleic Acid Testing.

**ARKRAY, Inc.**  
Yousuien-nai, 59 Gansuin-cho, Kamigyo-ku, Kyoto 602-0008, JAPAN  
  
Design and Development of In vitro diagnostic reagents and reagent products, calibrators and control materials for Clinical Chemistry, Immunochemistry, Infectious Immunology, Genetic Testing and Lancing Device.  
Design and Development of In vitro diagnostic instruments for Clinical Chemistry, Immunochemistry and Nucleic Acid Testing.

**ARKRAY Global Business, Inc.**  
Kyoto Miyuki Bldg. 10F, 689 Takanna-cho, Nakagyo-ku, Kyoto, 604-8153 JAPAN  
  
Sales of In vitro diagnostic reagents and reagent products, calibrators and control materials for Clinical Chemistry, Immunochemistry, Genetic Testing and Lancing Device.  
Sales of In vitro diagnostic instruments for Clinical Chemistry, Immunochemistry and Nucleic Acid Testing.



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## **ARKRAY Marketing, Inc.**

Taiga Bldg. 5F, 1-20-20 Yotsuya, Shinjuku-ku, Tokyo,  
160-0004, JAPAN

Sales of In vitro diagnostic reagents and reagent products,  
calibrators and control materials for Clinical Chemistry,  
Immunochemistry, Infectious Immunology, Genetic Testing and  
Lancing Device.

Sales of In vitro diagnostic instruments for Clinical Chemistry,  
Immunochemistry and Nucleic Acid Testing.

## **ARKRAY Infinity, Inc.**

1480 Koji, Konan-cho, Koka-shi, Shiga 520-3306, JAPAN

Installation and Servicing of In vitro diagnostic instruments for  
Clinical Chemistry, Immunochemistry and Nucleic Acid Testing.

## **ARKRAY Industry, Inc.**

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

Production and Distribution of In vitro diagnostic reagents and  
reagent products, calibrators and control materials for Clinical  
Chemistry and Immunochemistry.

Production and Distribution of In vitro diagnostic instruments for  
Clinical Chemistry and Immunochemistry.

## **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 In vitro diagnostic reagents and  
reagent products, calibrators and control materials for Clinical  
Chemistry.

Production, Distribution and Servicing of In vitro diagnostic  
instruments for Clinical Chemistry.



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## **ARKRAY Industry West, Inc.**

Main Avenue Cor. 3rd Street, Cavite Economic Zone, Rosario,  
Cavite 4106, PHILIPPINES

Production and Distribution of In vitro diagnostic reagents and  
reagent products, calibrators and control materials for Clinical  
Chemistry and Lancing Device.  
Production and Distribution of In vitro diagnostic instruments for  
Clinical Chemistry.

## **ARKRAY Infinity, Inc.**

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

Servicing of In vitro diagnostic instruments for Clinical Chemistry,  
Immunochemistry and Nucleic Acid Testing.

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