



# Certificate

No. Q5 115429 0001 Rev. 00

**Holder of Certificate:** **ARKRAY Healthcare Pvt Ltd**  
Plot No 336, 338 and 340, Road No.3  
G.I.D.C, Sachin  
Surat, Gujarat 394230  
INDIA

**Certification Mark:**



**Scope of Certificate:**

- Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents and Reagent Kits for Clinical Chemistry, Immunochemistry, Infectious Disease, Haematology, Immunohematology (Blood Grouping), Haemostasis reagents, Microbiology, Serology tests and Self-testing for Clinical Chemistry.
- Manufacture, Installation, Servicing and Distribution of In Vitro Diagnostic Instruments for IVD analyzers for Clinical Chemistry and Immunochemistry.
- The provision of Distribution, Installation, Repair and Maintenance Services for In vitro Diagnostic Instruments.
- The provision of Distribution Service for In vitro diagnostic reagents and reagent kits.

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 115429 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 115429 0001 Rev. 00)

**Report No.:** IND2022158

**Valid from:** 2022-09-08

**Valid until:** 2025-09-07

**Date,** 2022-09-08



Christoph Dicks  
Head of Certification/Notified Body

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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 Healthcare Pvt.Ltd  
C-90, Bldg No-5, Akshay Mittal Ind., Premises Co-Op Soc. Ltd  
Near Marol Naka, Andheri Kurla Road, Andheri East, Mumbai -  
Maharashtra 400059, INDIA

The provision of Distribution Service for In vitro Diagnostic  
Instruments

The provision of Distribution Service for In vitro diagnostic  
reagents and reagent kits

Warehouse for above device categories

ARKRAY Healthcare Pvt Ltd  
Plot No 336, 338 and 340, Road No.3, G.I.D.C, Sachin, Surat,  
Gujarat 394230, INDIA

Design and Development, Manufacture and Distribution of In Vitro  
Diagnostic Reagents and Reagent Kits for

- Clinical Chemistry (Biochemistry analytes)
- Immunochemistry (Cardiac markers, Autoimmune status,  
Immune Status, Disease status)
- Infectious Disease (including transmissible agents)
- Haematology (Compatibility testing, blood analytes)
- Immunohematology (Blood grouping)
- Haemostasis Reagent (Coagulation)
- Microbiology
- Serology tests
- Self-testing for Clinical Chemistry (Blood Glucose Monitoring  
Strips and Controls)

Manufacture, Installation, Servicing and Distribution of In Vitro  
Diagnostic Instruments for IVD analyzers for Clinical Chemistry  
and Immunochemistry.

The provision of Distribution, Installation, Repair and Maintenance  
Services for In vitro Diagnostic Instruments.

The provision of Distribution Service for In vitro diagnostic  
reagents and reagent kits.

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