



# Certificate

No. Q5 010283 0640 Rev. 01

**Holder of Certificate:** **Roche Diagnostics GmbH**  
Sandhofer Strasse 116  
68305 Mannheim  
GERMANY

**Certification Mark:**



**Scope of Certificate:** Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Software/Consumables used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Drug Abuse Screening, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Blood Components, Blood Gases, Electrolytes and Metabolites, Coagulation, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Fertility Testing, Pregnancy Testing, for Immunological Typing and Therapeutic Drug Monitoring and of In-Vitro Diagnostic Systems used in Diabetes Care for Blood Glucose Monitoring

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 010283 0640 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_010283_0640_Rev.01)

**Report No.:** 713224042-1

**Valid from:** 2021-10-25

**Valid until:** 2024-06-29

**Date,** 2021-10-25



Christoph Dicks  
Head of Certification/Notified Body

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No. Q5 010283 0640 Rev. 01

**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):** **Roche Diagnostics GmbH**  
**Sandhofer Strasse 116, 68305 Mannheim, GERMANY**

Design and Development of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Consumables used in Diagnosis and Management of Disease Status, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Coagulation and Pregnancy Testing, and of In-Vitro Diagnostics Systems used in Diabetes Care for Blood Glucose Monitoring, and Manufacture of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers and Distribution of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Software/Consumables used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Drug Abuse Screening, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Blood Components, Blood Gases, Electrolytes and Metabolites, Coagulation, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Fertility Testing, Pregnancy Testing, and for Immunological Typing and Therapeutic Drug Monitoring and of In-Vitro Diagnostic Systems used in Diabetes Care for Blood Glucose Monitoring

**Roche Diagnostics GmbH**  
**Nonnenwald 2, 82377 Penzberg, GERMANY**

Design and Development of In-Vitro Diagnostic Test Kits and Consumables for In-Vitro Diagnostic Analyzers used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Drug Abuse Screening, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Blood Components, Blood Gases, Coagulation, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Fertility Testing, Pregnancy Testing, and for Immunological Typing and Therapeutic Drug Monitoring and Manufacture of In-Vitro Diagnostic Test Kits used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Blood Components, Coagulation, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Fertility Testing, Pregnancy Testing, and for Immunological Typing and Therapeutic Drug Monitoring



Product Service

# Certificate

No. Q5 010283 0640 Rev. 01

## Facility(ies):

**Roche Diagnostics International Ltd  
Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND**

Design and Development of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Software/Consumables used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Drug Abuse Screening, Cardiac Markers, Endocrine Disorders, Blood and Urine Analytes, Blood Components, Blood Gases, Electrolytes and Metabolites, Coagulation, Donor Screening, Transmissible Agents, Sexually Transmissible Agents, Fertility Testing, Pregnancy Testing, and for Immunological Typing and Therapeutic Drug Monitoring and of In-Vitro Diagnostic Systems used in Diabetes Care for Blood Glucose Monitoring

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