



Product Service

Certificate

No. Q5 010283 0640 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design, 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, Drugs of Abuse, 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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_010283_0640_Rev.00)

Report No.: 713209683

Valid from: 2021-06-30

Valid until: 2024-06-29

Date, 2021-06-21

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): **Roche Diagnostics GmbH Centralised and Point of Care
Solutions
Sandhofer Strasse 116, 68305 Mannheim, GERMANY**

Design and Distribution of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Software/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 and Distribution of In-Vitro Diagnostic Test Kits and In-Vitro Diagnostic Analyzers/Software used in Diagnosis and Management of Cancer, Prenatal Screening, Immune Status, Disease Status, Autoimmune Status, Drugs of Abuse, 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 Diagnostics Systems used in Diabetes Care for Blood Glucose Monitoring

**Roche Diagnostics GmbH Centralised and Point of Care
Solutions
Nonnenwald 2, 82377 Penzberg, GERMANY**

Design 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, Drugs of Abuse, 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

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Facility(ies):

**Roche Diagnostics International Ltd Centralised and Point of
Care Solutions
Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND**

Design 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, Drugs of Abuse, 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

Parameters: ./.