



Product Service

# CERTIFICATE

No. Q1N 17 03 10283 383



**Holder of Certificate:** Roche Diagnostics GmbH

Sandhofer Strasse 116  
68305 Mannheim  
GERMANY

Rodney James Ward

Tổng Giám Đốc

**Certification Mark:**



**Scope of Certificate:**

Design, Manufacture, Distribution and Life Cycle Management 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). See also notes overleaf.

**Report No.:** 713098599-1

**Valid from:** 2017-05-10

**Valid until:** 2019-05-31



**Date,** 2017-05-10

*S. Preiß*

Stefan Preiß

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Product Service

## CERTIFICATE

No. Q1N 17 03 10283 383

**Applied Standard(s):** EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

**Facility(ies):**

- Roche Diagnostics GmbH Centralised and Point of Care Solutions  
Sandhofer Strasse 116, 68305 Mannheim, GERMANY
- Roche Diagnostics GmbH Centralised and Point of Care Solutions  
Nonnenwald 2, 82377 Penzberg, GERMANY
- Roche Diagnostics GmbH Distribution Center Instruments  
Industriestrasse 26, 67136 Fußgönheim, GERMANY
- Roche Diagnostics International Ltd Centralised and Point of Care  
Solutions  
Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND







Product Service

# CERTIFICATE

No. Q5 17 05 51951 018

Rodney James Ward

Tổng Giám Đốc

**Holder of Certificate: Roche Diagnostics International Ltd**

Forrenstrasse 2  
6343 Rotkreuz  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Manufacturing, Packaging, Release, Installation, Servicing and Support of Laboratory Instruments and Software for In-Vitro Diagnostic Systems, Laboratory Information Systems, Data Management and Work Area Management, Reagents for In-Vitro Diagnostic Systems used for the Diagnosis and Management of Immune, Autoimmune or Disease Status, Cancer, Therapeutic Drug Monitoring, Drugs of Abuse, Cardiac Markers, Protein Metabolism, Endocrine Disorders, Blood and Urine Analysis, Coagulation, Blood Gases, Electrolytes and Metabolites, Blood Donation Screening, Transmissible Agents including Sexually Transmissible Agents and Infectious Diseases, Viral and Microbial Infectious Diseases, Genetic and Fertility Testing

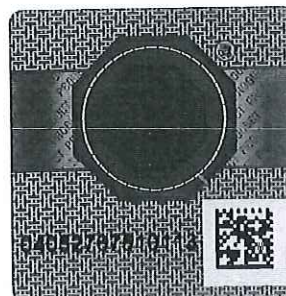


The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713104686

Valid from: 2017-07-01

Valid until: 2020-06-30



Date, 2017-06-27

*S. Preiß*

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Product Service

**CERTIFICATE****No. Q5 17 05 51951 018**

**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 International Ltd  
 Forrenstrasse 2, 6343 Rotkreuz, SWITZERLAND

Roche Diagnostics IT Solutions GmbH  
 Pascalstraße 10, 10587 Berlin, GERMANY

Roche Diagnostics SL, SIS  
 Avinguda de la Generalitat 163, Sant Cugat del Vallès, 08174  
 Barcelona, SPAIN

Roche PVT GmbH  
 Maybachstr. 30, 71332 Waiblingen, GERMANY

Roche PVT GmbH  
 Salamanderpl. 2-6, 70806 Kornwestheim, GERMANY

Roche PVT GmbH  
 Bernhardslaicher Weg 10, 71686 Remseck, GERMANY

