

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

# CERTIFICATE

No. Q1N 17 03 10283 383



**Holder of Certificate:** Roche Diagnostics GmbH

Sandhofer Strasse 116  
68305 Mannheim  
GERMANY

**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

Page 1 of 2





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



Page 2 of 2

**DAKKS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TUV®



# CERTIFICATE

Management system as per

## DIN EN ISO 13485:2012

Evidence of conformity with the above standard(s) has been furnished and is certified in accordance with TÜV PROFICERT procedures for

SAO Y BẢN CHÍNH  
Ngày.....Năm.....



Rodney James Ward

Tổng Giám Đốc

# RIEGLER

Riegler GmbH & Co. KG

Bahnhofstraße 80  
D-64367 Mühlthal  
GERMANY

Röhrstraße 1  
D-64372 Ober-Ramstadt  
GERMANY

An der Papiermühle 2  
D-64367 Mühlthal  
GERMANY

scope:

Development and production of plastic parts for the Medical technology in injection molding and blow molding. Mold making, assembly and finishing, clean room technology in production and assembly.

Certificate registration No. **73 105 5377**

Certificate valid from 2016-10-31 to **2019-10-30**

Audit report No. 4309 6114



*R. Maier*  
Darmstadt, 2016-10-31  
Certification body of TÜV Hessen  
- Head of Certification body -