ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 18 03 10283 394

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

Certification Mark:

tuv-sud.com/ps-cert

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). See also notes overleaf.

Report No.: 713120943-1

Valid from: 2018-06-30
Valid until: 2021-06-29

Date, 2018-06-19

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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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

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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