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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

Certificate

No. Q5 051951 0018 Rev. 02

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.: 713174107

Valid from: 2020-07-01

Valid until: 2023-06-30

Date, 2020-06-30

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 051951 0018 Rev. 02

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

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Barcelona, SPAIN

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Albert-Ruprecht-Strasse 2, 71636 Ludwigsburg, GERMANY

Parameters: .\.