

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: CK
Creatine Kinase

Art.-Nr./Cat. No.: 07190794190

Beschreibung/Description (1):
In-vitro-Test zur quantitativen Bestimmung von Creatinkinase (CK) in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen.
In vitro test for the quantitative determination of creatine kinase (CK) in human serum and plasma on Roche/Hitachi cobas c systems.

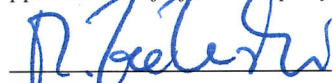
Beschreibung/Description (2):
In-vitro-Test zur quantitativen Bestimmung von Creatinkinase (CK) in Humanserum und -plasma mit COBAS INTEGRA Systemen.
In vitro test for the quantitative determination of creatine kinase (CK) in human serum and plasma on COBAS INTEGRA systems.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostika entspricht.
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 19 April 2016

Roche Diagnostics GmbH

ppa./on behalf of the company

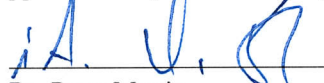


Ralf Zierenski

Head of Quality

Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Peter Martin

Senior Director Global Regulatory Affairs

Centralised and Point of Care Solutions

Kontaktadresse/Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim