

**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 Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Centralized Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)

Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: CREJ2
Creatinine Jaffé Gen. 2 (STAT, compensated)

Art.-Nr./Id. No.: 04810716

Beschreibung/Description (1): In vitro Test zur quantitativen Bestimmung von Creatinin in Urin mit COBAS INTEGRA Systemen.
In vitro test for the quantitative determination of creatinine in urine on COBAS INTEGRA systems.

Beschreibung/Description (2): In vitro Test zur quantitativen Bestimmung der Creatininkonzentration in Humanserum, -plasma und -urin mit Roche/Hitachi cobas c Systemen.
In vitro test for the quantitative determination of creatinine concentration in human serum, plasma and urine on Roche/Hitachi cobas c 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-Diagnostica 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, 09.08.2006

Roche Diagnostics GmbH

ppa./on behalf of the company

Dr. M. Thein
Head of Quality Management &
Regulatory Affairs
Centralized Diagnostics

i. V./on behalf of the company

A. Schenkel
Head of Quality Assurance
Centralized Diagnostics

Kontaktadresse/Contact address: Roche Centralized Diagnostics
Abt./Dept. Regulatory Affairs
Sandhofer Straße 116
D-68305 Mannheim
Fax: +49 621/759 1448

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