



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: ISE Internal Standard Gen.2

Art.-Nr./Id. No.: 04522320

Beschreibung/Description:

Das ISE-Modul der Roche/Hitachi cobas c Systeme dient zur quantitativen Bestimmung von Natrium, Kalium und Chlorid in Serum, Plasma oder Urin mittels ionenselektiver Elektroden.

The ISE module of the Roche/Hitachi cobas c systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma or urine using ion-selective electrodes.

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.

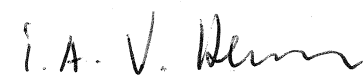
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 12.06.2006

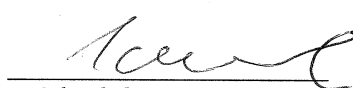
Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company



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



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

iseinternalstandardgen2_1.doc-AJ