



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: CHE2
Cholinesterase Gen.2

Art.-Nr./Id. No.: 04498577

Beschreibung/Description (1): In vitro Test zur quantitativen Bestimmung der katalytischen Aktivität der Cholinesterase (EC 3.1.1.8; Acylcholinacylhydrolase) in Serum und Plasma.
In vitro test for the quantitative determination of the catalytic activity of cholinesterase (EC 3.1.1.8; acylcholine acylhydrolase) in serum and plasma.

Beschreibung/Description (2): In vitro Test zur quantitativen Bestimmung der Cholinesterase in Humanserum und -plasma mit Roche/Hitachi cobas c Systemen.
In vitro assay for the quantitative determination of cholinesterase in human serum and plasma 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, 17.08.2006

Roche Diagnostics GmbH

ppa./on behalf of the company

Dr. M. Thein
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i. V./on behalf of the company

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