

EC Declaration of Conformity

as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Manufacturer: Roche Diagnostics GmbH
Address: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

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

Product name: CRPHS
C-Reactive Protein (Latex) High Sensitive Assay

Id. No.: 05401607

Description: In vitro Test zur quantitativen Bestimmung von C-reaktivem Protein (CRP) in Humanserum und -plasma mit dem cobas c 111 System.
In vitro test for the quantitative determination of C-reactive protein (CRP) in human serum and plasma on the cobas c 111 system.

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.

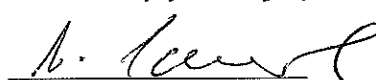
Mannheim, 17.12.2008
Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. M. Thein
Head of Quality & Regulatory
Management
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i. V./on behalf of the company



A. Schenkel
Head of Quality Control
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