



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 Professional 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: **Calibrator for automated systems**

Art.-Nr./Id. No.: **10759350**

Beschreibung/Description:
Calibrator for automated systems (C.f.a.s.) wird zur Kalibration von quantitativen Roche-Methoden an klinisch-chemischen Analysengeräten von Roche wie in den Wertebölgern angegeben verwendet.
Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

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, 26.10.2011

Roche Diagnostics GmbH
ppa./on behalf of the company

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Head of Quality
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i. V./on behalf of the company

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