Roche

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
68305 Mannheim
Germany

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*: **AssayTip**

Art.-Nr./*Id. No.*: 11706799001

Beschreibung/*Description*: The AssayTip is intended to be used as an IVD accessory on the following systems:
cobas e 411 analyzer
Elecsys® 2010 analyzer

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, 30. Jul. 2013
Roche Diagnostics GmbH
ppa./*on behalf of the company*

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Rotkreuz, 30. Jul. 2013
Roche Diagnostics International Ltd
ppa./*on behalf of the company*

S. Braun
Susanne Braun for
Ralf Zielenski
Head of Quality GPS and RDI
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