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*:	**Sample Cup**
Art.-Nr./*Id. No.*:	10394246001
Beschreibung/*Description*:	The Sample Cup is intended to be used as IVD accessory on the following systems: COBAS INTEGRA® 400 plus analyzer; COBAS INTEGRA® 800 analyzer; Roche/Hitachi 902 analyzer; Roche/Hitachi 912 analyzer; Roche/Hitachi 917 analyzer; MODULAR® P, D analyzer(s); - MODULAR® PRE-ANALYTICS; cobas c 111 analyzer; cobas c 311 analyzer; cobas c 501 module; cobas c 502 module; cobas c 701 module; cobas c 702 module; MODULAR® ANALYTICS EVO; Elecsys® 2010 analyzer; cobas e 411 analyzer; cobas e 601 module; cobas e 602 module

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. Sep 2013
Roche Diagnostics GmbH
ppa./*on behalf of the company*

i.V.

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Rotkreuz, 10. Sept. 2013
Roche Diagnostics International Ltd
ppa./*on behalf of the company*

Ralf Zielenski
Head of Quality GPS and RDI
Roche Diagnostics International Ltd

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