



## 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 Parliament 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: **AssayCup**  
Art.-Nr./Id. No.: 11706802001  
Beschreibung/Description: The AssayCup 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

Ralf Zielenski  
Head of Quality GPS and RDI  
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