



## 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: **cobas® cup blue**  
Art.-Nr./Id. No.: 21044869001  
Beschreibung/Description: The cobas® cup blue are intended to be used as an IVD-  
accessory on the following systems:  
COBAS INTEGRA® 400 plus analyzer  
COBAS INTEGRA® 800 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, 17. Sep 2013  
Roche Diagnostics GmbH  
ppa./on behalf of the company

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

s.v.   
Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics

  
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