

## **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: Sandhofer Strasse 116  
68305 Mannheim  
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie  
*Roche Diagnostics GmbH declares that the product/the product line*

Produktname/Product name: **RD Standard False Bottom Tube**

Art.-Nr./Cat. No.: **04740955001**

Beschreibung/Description: The RD Standard False Bottom Tube is intended to be used as an IVD accessory on the following systems:  
**MODULAR P** analyzer; **MODULAR PRE-ANALYTICS**; **MODULAR D** analyzer; **MODULAR ANALYTICS E170**; Elecsys® 2010 analyzer (rack system); **cobas c 111** analyzer; **cobas c 311** analyzer; **cobas c 501** module; **cobas c 502** module; **cobas c 701** module; **cobas c 702** module; **cobas e 411** analyzer (rack system); **cobas e 411** analyzer (disk system); **cobas e 601** module; **cobas e 602** module, **cobas e 801** module

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).*

Mannheim, 14 June 2016

Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

ppa./on behalf of the company



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