



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: Assay Tip/Assay Cup
Art.-Nr./Id. No.: 12102137001
Beschreibung/Description: The Assay Tip/Assay Cup is used as an IVD-accessory on the following systems:
E170 module
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, 04. Nov. 2013
Roche Diagnostics GmbH
ppa./on behalf of the company

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

ppa./on behalf of the company

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

Kontaktadresse/Contact address: Roche Professional Diagnostics
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
68305 Mannheim
Germany
Fax: +49 621/759 1448

