



EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV Product Service als Notified Body (Nr. 0123)
as per Annex IV of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 via TÜV Product Service as the Notified Body (No. 0123)

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: 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® HBV/HCV/HIV-1 Control Kit
For use on the cobas® 6800/8800 Systems

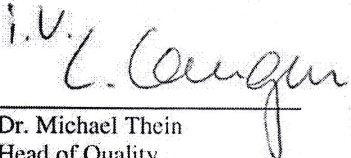
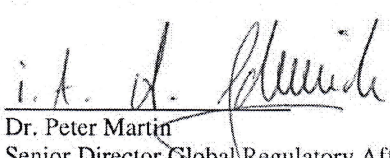
Art.-Nr./Cat. No.: 06997767190

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-Diagnostika 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, 03 December 2014

Roche Diagnostics GmbH

ppa./on behalf of the company *ppa./on behalf of the company*

<i>i.v.</i> 	
Dr. Michael Thein Head of Quality Professional Diagnostics	Dr. Peter Martin Senior Director Global Regulatory Affairs Professional Diagnostics

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