

## **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: Hitachi High-Technologies Corporation  
1-24-14 Nishi-Shimbashi  
Minato-ku Tokyo 105-8717  
Japan

Authorized Representative: Roche Diagnostics GmbH  
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® e 411**

Art.-Nr./Id. No.: Rack Version: 04775201001  
Disk Version: 04775279001


Beschreibung/Description: Immunoassay analyzer for human liquids.  
In-vitro diagnostic medical product.

**cobas® e411** is an automated, random access analyzer for heterogeneous immunoassays of patient samples with the Electro Chemiluminescence (ECL) method.

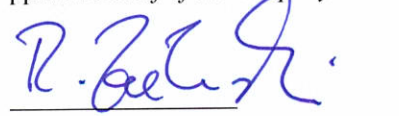
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.

*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, 11. Feb. 2014  
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