

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.

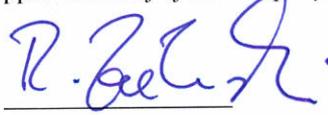
cobas® e411 is an automated, random access analyzer for heterogeneous immunoassays of patient samples with the Electro Chemiluminescence (ECL) method.

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