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**® **e**411 is an automated, random access analyzer for heterogeneous immunoassays of patient samples with the Electro Chemiluminescense (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