Roche

Diagnostics

EC- Declaration of Conformity

According to Annex III of the Directive 98/79/EC of the European Parliament and of the Council of 27. October 1998

Manufacturer:

Hitachi High-Technologies Corporation
1-24-14 Nishi-Shinbashi
Minato-ku, Tokyo 105-8717, Japan

Authorised Representative:

Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim, Germany

Roche Diagnostics GmbH declares that the in vitro diagnostic medical instrument

Product name: **cobas® e 411**

Description: Immunology analyzer for automated in-vitro analysis of patient samples with the Electro Chemiluminescense (ECL) method.

relating to this declaration, complies with the requirements of EC Directive 98/79/EC of the Council of October 27, 1998 concerning in-vitro diagnostic medical devices.

Mannheim, October 19, 2006

Roche Diagnostics GmbH

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