

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 Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **Sample Cup**

Art.-Nr./Cat. No.: **10394246001**

Beschreibung/Description: The Sample Cup is intended to be used as an IVD accessory on the following systems:
COBAS INTEGRA® 400 plus analyzer; COBAS INTEGRA® 800 analyzer; **MODULAR** P, D analyzer(s); **MODULAR** PRE-ANALYTICS; **MODULAR ANALYTICS EVO** E170;
Elecsys® 2010 analyzer; **cobas c** 111 analyzer; **cobas c** 311 analyzer; **cobas c** 501 module; **cobas c** 502 module; **cobas c** 701 module; **cobas c** 702 module; **cobas e** 411 analyzer (rack system); **cobas e** 411 analyzer (disk system); **cobas e** 601 module; **cobas e** 602 module; **cobas e** 801 module;

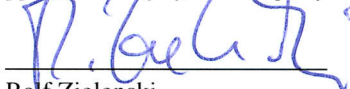
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 14 June 2016

Roche Diagnostics GmbH

ppa./on behalf of the company

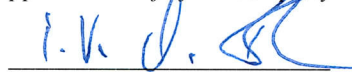


Ralf Zielenski

Head of Quality

Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Peter Martin

Senior Director Global Regulatory Affairs

Centralised and Point of Care Solutions

Kontaktadresse/Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
68305 Mannheim
Germany