

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: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
D-68305 Mannheim

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

Produktname/Product name: **ACET2 calibrator**

Art.-Nr./Cat. No.: **07007515190**

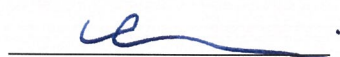
Beschreibung/Description: Der ACET2 Kalibrator dient zur Kalibrierung des
Acetaminophen Gen.2 Tests von Roche.
*ACET2 calibrator is for use in the calibration of the
Acetaminophen Gen.2 Roche assay.*

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-Diagnostika 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, 23 June 2015

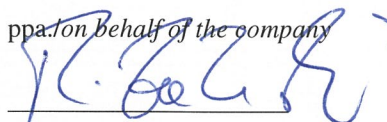
Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. Peter Martin
Senior Director Global Regulatory Affairs
Roche Professional Diagnostics

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
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