

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: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

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: **T3 CalSet**

Art.-Nr./Id. No.: **11731548**

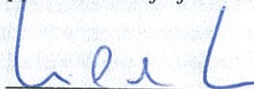
Beschreibung/Description: T3 CalSet wird zur Kalibration des quantitativen Elecsys T3 Tests auf Elecsys und cobas e Immunoassay-Systemen verwendet.
T3 CalSet is used for calibrating the quantitative Elecsys T3 assay on the Elecsys and cobas e immunoassay analyzers.

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, 25.07.2013

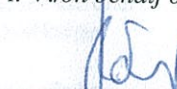
Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

i. V./on behalf of the company



Dr. C. Fleischer
Head of Quality Control Penzberg
Roche Diagnostics Global Operations

Kontaktadresse/Contact address: Roche Professional Diagnostics
Abt./Dept. Global Regulatory Affairs
Sandhofer Straße 116
D-68305 Mannheim
Fax: +49 621/759 1448

11731548_T3 CalSet - Ia

Roche Diagnostics GmbH Diagnostics Division

Roche Diagnostics GmbH; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher: Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

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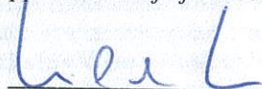
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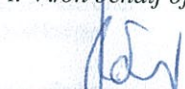
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Produktname/Product name: **AssayTip**
Art.-Nr./Id. No.: 11706799001
Beschreibung/Description: The AssayTip is intended to be used as an IVD accessory on the following systems:
cobas e 411 analyzer
Elecsys® 2010 analyzer

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.
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Mannheim, 30. Jul. 2013
Roche Diagnostics GmbH
ppa./on behalf of the company

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Rotkreuz, 30. Jul. 2013
Roche Diagnostics International Ltd
ppa./on behalf of the company

Ralf Zielenski
Head of Quality GPS and RDI
Roche Diagnostics International Ltd

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Produktname/Product name: **AssayCup**
Art.-Nr./Id. No.: 11706802001
Beschreibung/Description: The AssayCup is intended to be used as an IVD accessory on the following systems:
cobas e 411 analyzer
Elecsys® 2010 analyzer

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