



EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)

as per Annex IV of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)

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: **Anti-HCV II**
Art.-Nr./Id. No.: 06368921
Beschreibung/Description: Anti-HCV II ist ein diagnostischer in vitro Test für den qualitativen Nachweis von Antikörpern gegen Hepatitis C Virus (HCV) in Humanserum und -plasma.
Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys sowie cobas e Immunoassay-Systemen vorgesehen.
*Anti-HCV II is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.*

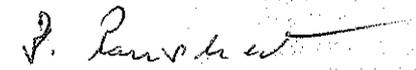
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils 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, 22. Dezember 2011

Roche Diagnostics GmbH
ppa./on behalf of the company

i. V./on behalf of the company


Dr. M. Thein
Head of Quality
Roche Professional Diagnostics


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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



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)
(List A)

No. V7 11 12 10283 262

Manufacturer: Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
GERMANY

Product: Screening test for Hepatitis C marker

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. See also notes overleaf.

Report No.: 71393026

Valid from: 2011-12-21
Valid until: 2016-12-20



Date, 2011-12-22

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4)
(List A)

No. V7 11 12 10283 262

Model(s): Anti-HCV II
Elecsys and cobas e analyzers

Parameters:	Model Name:	Model No.:
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	Anti-HCV II	06368921
	Anti-HCV II	06427405

Elecsys and cobas e analyzers

Facility(ies): Roche Diagnostics GmbH
Sandhofer Str. 116, 68305 Mannheim, GERMANY