

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: 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: **Vitamin B12 II**

Art.-Nr./Id. No.: **07212771190**

Beschreibung/Description:
In-vitro-Bindungstest zur quantitativen Bestimmung von Vitamin B12 in Humanserum und -plasma.
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und **cobas e** Immunoassay-Systemen vorgesehen.
*Binding assay for the in vitro quantitative determination of vitamin B12 in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.*

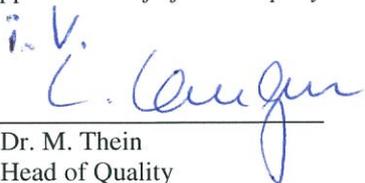
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils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

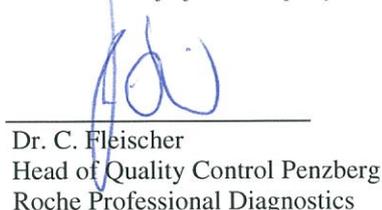
Mannheim, 26 March 2015

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


Dr. C. Fleischer
Head of Quality Control Penzberg
Roche Professional Diagnostics

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