

## **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: 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: **PreciControl HBsAg II quant II**

Art.-Nr./Cat. No.: **07143745190**

Beschreibung/Description: PreciControl HBsAg II quant II dient zur Qualitätskontrolle des Elecsys HBsAg II quant II Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen./  
*PreciControl HBsAg II quant II is used for quality control of the Elecsys HBsAg II quant II immunoassay 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-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, 15 April 2015

Roche Diagnostics GmbH

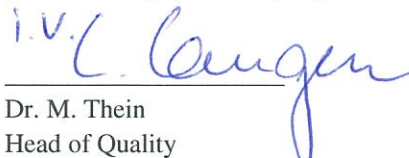
*ppa./on behalf of the company*

A handwritten signature in blue ink, appearing to read "i.v. Z. C. S.", written over a horizontal line.

Dr. Peter Martin

Senior Director Global Regulatory Affairs  
Roche Professional Diagnostics

*ppa./on behalf of the company*

A handwritten signature in blue ink, appearing to read "i.v. C. Thein", written over a horizontal line.

Dr. M. Thein

Head of Quality  
Roche Professional Diagnostics

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