

## **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:** **HDLC4**  
HDL-Cholesterol Gen.4

**Art.-Nr./Cat. No.:** **07528566190**

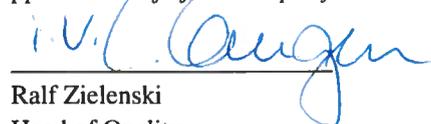
**Beschreibung/Description:** In-vitro-Test zur quantitativen Bestimmung der HDL-  
Cholesterinkonzentration in Humanserum und -plasma mit  
Roche/Hitachi **cobas c** Systemen.  
*In vitro diagnostic test for the quantitative determination of the  
HDL-cholesterol concentration in human serum and plasma on  
Roche/Hitachi **cobas c** systems.*

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments  
und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der  
Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.  
*to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and  
Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the  
national laws of the Member States in which the device is intended to be placed on the market).*

Mannheim, 19 January 2017

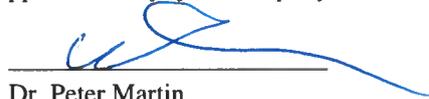
Roche Diagnostics GmbH

*ppa./on behalf of the company*



Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

*ppa./on behalf of the company*



Dr. Peter Martin  
Senior Director Global Regulatory Affairs  
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