



## EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller/ Manufacturer: Roche Diagnostics GmbH

Adresse/ Address: Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

Roche Diagnostics GmbH erklärt, dass das Produkt / die Produktfamilie  
Roche Diagnostics hereby declares that the product / family of products

**ACCU-CHEK® Performa Blutglukose Messsystem, bestehend aus:**  
**ACCU-CHEK® Performa blood Glucose monitoring system, consisting of:**

**Produktname: ACCU-CHEK® Performa mg/dL Kit 05894930**

**Product name: ACCU-CHEK® Performa mg/dL Kit 06454186**

**ACCU-CHEK Performa mg/dL Kit 06332927**

**ACCU-CHEK Performa mg/dL Kit 06276814**

**ACCU-CHEK Performa mg/dL Kit 07050844**

**ACCU-CHEK® Performa (Model NC) mg/dL Kit 06987788**

**ACCU-CHEK® Performa mmol/L Kit 05894948**

**ACCU-CHEK® Performa mmol/L Kit 06454313**

**ACCU-CHEK® Performa (Model NC) mmol/L Kit 06987796**

**ACCU-CHEK® Performa mg/dL meter only 05894972**

**ACCU-CHEK® Performa mg/dL meter only 06454208**

**ACCU-CHEK® Performa (Model NC) mg/dL meter only 06987834**

**ACCU-CHEK® Performa (Model NC) mmol/L meter only 06988059**

**ACCU-CHEK® Performa mmol/L meter only 05894999**

**ACCU-CHEK® Performa mmol/L meter only 06454330**

**ACCU-CHEK® Performa (Model NC) mg/dL Set 06988032**

**ACCU-CHEK® Performa (Model NC) mmol/L Set 06988547**

ACCU-CHEK® Performa Nano mg/dL Kit 05955874  
ACCU-CHEK® Performa Nano mg/dL Kit 06454275  
ACCU-CHEK® Performa Nano mmol/L Kit 05955882  
ACCU-CHEK® Performa Nano mmol/L Kit 06454348  
ACCU-CHEK® Performa Nano mg/dL meter only 05955939  
ACCU-CHEK® Performa Nano mg/dL meter only 06454305  
ACCU-CHEK® Performa Nano mmol/L meter only 05955947  
ACCU-CHEK® Performa Nano mmol/L meter only 06454364  
ACCU-CHEK® Performa Nano mmol/L Set 06454356  
ACCU-CHEK® Performa Combo mg/dL Set 05947138  
ACCU-CHEK® Performa Combo mg/dL Set 05151961  
ACCU-CHEK® Performa Combo mg/dL Set 05075815  
ACCU-CHEK® Performa Combo mmol/L Set 05947120  
ACCU-CHEK® Performa Combo mmol/L Set 05075785  
ACCU-CHEK® Performa Connect mg/dL Kit 07049919  
ACCU-CHEK® Performa Connect mmol/L Kit 07049935  
ACCU-CHEK® Performa Connect mg/dL Set 07049927  
ACCU-CHEK® Performa Connect mg/dL meter only 07049811  
ACCU-CHEK® Performa Connect mmol/L Set 07049943  
ACCU-CHEK® Performa Connect mg/dL meter only 07430779  
ACCU-CHEK® Performa Insight (Diabetes Manager)  
ACCU-CHEK® Performa Expert

**Beschreibung:** Messgeräte zum Zwecke der Überwachung der Blutglucosekonzentration im menschlichen Blut.

**Description:** Meters for the purpose of monitoring glucose concentration in human blood.

**Produktname:** ACCU-CHEK® Performa 05987245 (10 tests)

**Product name:** ACCU-CHEK® Performa 06453996 (10 tests)

ACCU-CHEK® Performa 05987261 (25 tests)

ACCU-CHEK® Performa 06454003 (25 tests)

ACCU-CHEK® Performa 06454011 (50 tests)

**ACCU-CHEK® Performa 05987270 (50 tests)**

**ACCU-CHEK® Inform II 05942861 (50 tests)**

**ACCU-CHEK® Performa 05987288 (100 tests)**

**ACCU-CHEK® Performa 06454038 (100 tests)**

**Beschreibung:** Teststreifen zur quantitativen Blutzuckerbestimmung mit dem Messgerät ACCU-CHEK® Performa.

**Description:** Test strips for quantitative blood glucose determination with ACCU-CHEK® Performa blood glucose monitors.

**Produktname:** ACCU-CHEK® Performa Control

**Product name:**

**Beschreibung:** Kontrolllösungen zur Funktionskontrolle von Blutglukose Messgeräten und Teststreifen.

**Description:** Control solution for carrying out performance checks on blood glucose monitors and test strips.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 über In-Vitro-Diagnostika entspricht; gemäß Anhang IV der Richtlinie als Konformitätsbewertungsverfahren unter Beteiligung der Benannten Stelle LRQA mit der Nummer 0088.

to which this declaration relates, complies with the Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices using Annex IV as the conformity assessment procedure via LRQA ( NB 0088 ) as the Notified Body.

**Kontaktadresse:** Roche Diagnostics GmbH  
**Contact address:** Abt. Qualitätsmanagement, DCPQ  
Sandhofer Strasse 116  
68305 Mannheim  
Germany  
Telefax: +49 621 759 3801

Mannheim, 15. April 2015

Roche Diagnostics GmbH

i.V./ On behalf of the company



**Christian Bohrt**

OUS Regulatory Affairs Diabetes Care  
OUS Regulatory Affairs Diabetes Care

i.V./ On behalf of the company



**Dr. Thomas Schmidt**

Leiter Qualität Diabetes Care Systeme  
Head of Quality Diabetes Care Systems