

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 Blutglukosekonzentration 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.

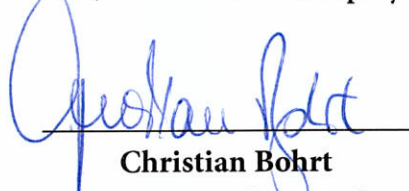
to which this declaration relates, complies with the Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices using Annex IV as the conformity assessment procedure via LRQA (NB 0088) as the Notified Body.

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Mannheim, 15. April 2015

Roche Diagnostics GmbH

i.V./ On behalf of the company



Christian Bohrt

OUS Regulatory Affairs Diabetes Care
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i.V./ On behalf of the company



Dr. Thomas Schmidt

Leiter Qualität Diabetes Care Systeme
Head of Quality Diabetes Care Systems