

EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller / Manufacturer: Roche Diabetes Care GmbH

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

Roche Diabetes Care GmbH erklärt, dass die Produktfamilie
Roche Diabetes Care GmbH declares that the family of products

Accu-Chek® Performa Blutglukose Überwachungssystem, bestehend aus:
Accu-Chek® Performa Blood Glucose Monitoring System, consisting of:

Produktname / Product name:	Katalognummer / Catalog Number:
Accu-Chek® Performa (Model NC) mg/dL Kit	06987788
Accu-Chek® Performa (Model NC) mmol/L Kit	06987796
Accu-Chek® Performa (Model NC) mg/dL meter only	06987834
Accu-Chek® Performa (Model NC) mg /dL meter only (5 pcs)	07898533
Accu-Chek® Performa (Model NC) mmol/L meter only	06988059
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	06454275
Accu-Chek® Performa Nano mmol/L Kit	06454348
Accu-Chek® Performa Nano mg/dL meter only	06454305
Accu-Chek® Performa Nano mmol/L meter only	06454364
Accu-Chek® Performa Nano mmol/L Set	06454356
Accu-Chek® Performa Nano mg/dL Set	06454283
Accu-Chek® Performa Combo mg/dL Replacement Kit	05459001
Accu-Chek® Performa Combo mg/dL Replacement Kit	05520959
Accu-Chek® Performa Combo mg/dL Replacement Kit	07184506
Accu-Chek® Performa Combo mg/dL Replacement Kit	05899303
Accu-Chek® Performa Combo mmol/L Replacement Kit	05504660

Produktname / Product name:

Katalognummer / Catalog Number:

Accu-Chek® Performa Combo mmol/L Replacement Kit	05899311
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 mmol/L Set	07049943
Accu-Chek® Performa Connect mg/dL meter only	07049811
Accu-Chek® Performa Connect mg/dL meter only	07430779
Accu-Chek® Performa Insight Meter Kit mg/dL	07161492
Accu-Chek® Performa Insight Meter Kit mmol/L	07254334
Accu-Chek® Performa Insight Meter Kit mmol/L	07253931
Accu-Chek® Performa Insight Meter Kit mg/dL	07249110
Accu-Chek® Performa Insight Meter mmol/L Replacement Kit	07163231
Accu-Chek® Performa Insight Meter mg/dL Replacement Kit	07163258
Accu-Chek® Performa mg/dL meter only	05894972
Accu-Chek® Performa mmol/L meter only	05894999

Beschreibung / Description:

Das Accu-Chek® Performa Blutglukose Messgerät dient zusammen mit dem Accu-Chek® Performa Teststreifen zur Überwachung der Blutglukosekonzentration im menschlichen Blut. Das Blutglukoseüberwachungssystem ist sowohl für den Patientenselbsttest als auch für die professionelle Anwendung geeignet.

The Accu-Chek® Performa blood glucose meter is intended to be used for quantitative blood glucose tests in human blood and is intended to be used together with Accu-Chek® Performa test strips. The blood glucose monitoring system is suitable for patient self-testing and for professional use.

Produktname / Product name:

Katalognummer / Catalog Number:

Accu-Chek® Performa	06453996	(10 tests)
Accu-Chek® Performa	06454003	(25 tests)
Accu-Chek® Performa	06454011	(50 tests)
Accu-Chek® Inform II	05942861	(50 tests)
Accu-Chek® Performa	06454038	(100 tests)

Beschreibung / Description:

Der Accu-Chek® Performa Teststreifen dient zusammen mit einem Accu-Chek® Performa Blutglukose Messgerät zur Überwachung der Blutglukosekonzentration im menschlichen Blut. Das Blutglukoseüberwachungssystem ist sowohl für den Patientenselbsttest als auch für die professionelle Anwendung geeignet.

The Accu-Chek® Performa test strip is intended to be used for quantitative blood glucose tests in human blood and is intended to be used together with Accu-Chek® Performa blood glucose meters. The blood glucose monitoring system is suitable for patient self-testing and for professional use.

Produktname / Product name:

Katalognummer / Catalog Number:

Accu-Chek® Performa Control	04861736
Accu-Chek® Performa Control	05078164
Accu-Chek® Performa Control	05128030

Beschreibung / Description:

Kontrolllösungen zur Funktionskontrolle von Accu-Chek® Performa Blutglukose Messgeräten und Teststreifen.

Control solutions for carrying out performance checks on Accu-Chek® Performa 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 EC Directive 98/79/EC of October 27, 1998 on in vitro diagnostic medical devices using Annex IV as the conformity assessment procedure with the involvement of LRQA (NB 0088) as the Notified Body.

Diese EG Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 2. November 2016 in Verkehr gebracht werden.

This EC Declaration of Conformity is valid for all above mentioned products placed on the market beginning of 2. November, 2016.

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Mannheim, 27. Oktober 2016

Roche Diabetes Care GmbH

i.V. / On behalf of the company



Roland Hechler

Leiter OUS Regulatory Affairs Diabetes Care
Head of 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