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 unter seiner alleinigen Verantwortung, dass das Produkt / die Produktfamilie
Roche Diabetes Care GmbH declares under its sole responsibility that the product / family of products

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

Produktname / **Product name:**	Katalognummer / **Catalog Number:**
Accu-Chek® Instant mg/dL *Meter*	**07819340**
Accu-Chek® Instant mmol/L *Meter*	**07819358**

Beschreibung / **Description:**

Das Accu-Chek® Instant Blutglukose Messgerät dient zusammen mit dem Accu-Chek® Instant 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® Instant 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® Instant test strips.
The blood glucose monitoring system is suitable for patient self-testing and for professional use.

Roche Diabetes Care GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 720251 - Geschäftsführung: Michael Wöhler, Aufsichtsratsvorsitzender: Dr. Severin Schwan

Produktname / **Product name:**	Katalognummer / **Catalog Number:**	
Accu-Chek® Instant Test Strips	**07819366**	(10 tests)
Accu-Chek® Instant Test Strips	**07819374**	(25 tests)
Accu-Chek® Instant Test Strips	**07869517**	(30 tests)
Accu-Chek® Instant Test Strips	**07819382**	(50 tests)
Accu-Chek® Instant Test Strips	**07819404**	(100 tests)
Accu-Chek® Instant Test Strips	**08474168**	(6 x 50 tests)

Beschreibung / **Description:**

Der Accu-Chek® Instant Teststreifen dient zusammen mit einem Accu-Chek® Instant oder Accu-Chek® Instant S 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® Instant 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® Instant or Accu-Chek® Instant S 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® Instant *Controls*	**07869525**

Beschreibung / **Description:**

Kontrolllösungen zur Funktionskontrolle von Accu-Chek® Instant oder Accu-Chek® Instant S Blutglukose Messgeräten und Teststreifen.
Control solutions for carrying out performance checks on Accu-Chek® Instant or Accu-Chek® Instant S 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.

Die oben aufgeführten Produkte werden in verschiedenen Verpackungskonfigurationen sowie in Kombination mit anderen Produkten von Roche Diabetes Care GmbH, als Kit oder Set bezeichnet, in den Verkehr gebracht.

The above listed products are brought on the market in several package configurations as well as in combination with other products from Roche Diabetes Care GmbH, named Kit or Set.

Die Accu-Chek Instant System Komponenten sind in folgenden Kits enthalten:
The Accu-Chek Instant system components are packed into the following kits:

Accu-Chek Instant Kits and Sets

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
07819307039	Accu-Chek® Instant mg/dL Kit	07766858001 Accu-Chek® Instant mg/dL Meter (Bulk) 07819366173 Accu-Chek Instant test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07819307078 07819307446	Accu-Chek® Instant mg/dL Kit	07766858001 Accu-Chek® Instant mg/dL Meter (Bulk) 07819366078 Accu-Chek Instant test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07819307056	Accu-Chek® Instant mg/dL Kit	07766858001 Accu-Chek® Instant mg/dL Meter (Bulk) 07819366078 Accu-Chek Instant test strip (10 tests) 07523211001 Accu-Chek Fastclix Lancing Device 05208629001 Accu-Chek Fastclix (6 Lancets)
07819307080	Accu-Chek® Instant mg/dL Kit	07766858001 Accu-Chek® Instant mg/dL Meter (Bulk) 07819366173 Accu-Chek Instant test strip (10 tests) 07523211001 Accu-Chek Fastclix Lancing Device 05208629001 Accu-Chek Fastclix (6 Lancets)
07819315345	Accu-Chek® Instant mmol/L	07766947001 Accu-Chek® Instant mmol/L Meter (Bulk) 07819366173 Accu-Chek Instant test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07819315015 07819315340	Accu-Chek® Instant mmol/L	07766947001 Accu-Chek® Instant mmol/L Meter (Bulk) 07819366078 Accu-Chek Instant test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)
07819315057	Accu-Chek® Instant mmol/L Kit	07766947001 Accu-Chek® Instant mmol/L Meter (Bulk) 07819366173 Accu-Chek Instant test strip (10 tests) 07523211001 Accu-Chek Fastclix Lancing Device 05208629001 Accu-Chek Fastclix (6 Lancets)
07819307020	Accu-Chek® Instant mg/dL Kit	07766998001 Accu-Chek® Instant mg/dL Meter (Bulk) 07819366020 Accu-Chek Instant test strip (10 tests) 05181186001 Accu-Chek Softclix Lancing Device 03157482001 Accu-Chek Softclix (10 Lancets)

07819307023 07819307046	Accu-Chek® Instant mg/dL Kit	07767102001 07819366023 05181186001 03157482001	Accu-Chek® Instant mg/dL Meter (Bulk) Accu-Chek Instant test strip (10 tests) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)
07819323070	Accu-Chek® Instant mg/dL Set	07766858001 05181186001 03157482001	Accu-Chek® Instant mg/dL Meter (Bulk) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)
07819323023	Accu-Chek® Instant mg/dL Set	07766998001 05181186001 03157482001	Accu-Chek® Instant mg/dL Meter (Bulk) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)
07819323047	Accu-Chek® Instant mg/dL Set	07767102001 05181186001 03157482001	Accu-Chek® Instant mg/dL Meter (Bulk) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)
07819323036	Accu-Chek® Instant mg/dL Set	07766998001 07523211001 05208629001	Accu-Chek® Instant mg/dL Meter (Bulk) Accu-Chek Fastclix Lancing Device Accu-Chek Fastclix (6 Lancets)
07819331020	Accu-Chek® Instant mmol/L Set	07767005001 05181186001 03157482001	Accu-Chek® Instant mmol/L Meter (Bulk) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)
07819331119	Accu-Chek® Instant mmol/L Set	07767064001 05181186001 03157482001	Accu-Chek® Instant mmol/L Meter (Bulk) Accu-Chek Softclix Lancing Device Accu-Chek Softclix (10 Lancets)

Die in den Kits und Sets enthaltenen oben aufgeführten Medizinprodukte entsprechen den Forderungen der EG-Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte, geändert durch die EG-Richtlinie 2007/47/EG vom 5. September 2007; gemäß Anhang II der Richtlinie als Konformitätsbewertungsverfahren unter Beteiligung der Benannten Stelle LRQA mit der Nummer 0088.

The above mentioned medical devices contained in the Kits and Sets comply with the EC Directive 93/42/EEC of June 14, 1993 on medical devices, as amended by EC Directive 2007/47/EC of September 5, 2007 using Annex II as the conformity assessment procedure with the involvement of LRQA (NB 0088) as the Notified Body.

Diese EG Konformitätserklärung ist für alle oben aufgeführte Produkte gültig, das ab dem 15. Januar 2018 in Verkehr gebracht wird.

This EC Declaration of Conformity is valid for all the above mentioned products placed on the market beginning of 15. Januar 2018.

Kontaktadresse / **Contact address:**

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Mannheim, 15. Januar 2018

Roche Diabetes Care GmbH

i.V. / On behalf of the company

Christian Bohrt

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Dr. Thomas Schmidt

Leiter Qualität Diabetes Care Systeme
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