

EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller/ Manufacturer: Roche Diagnostics GmbH

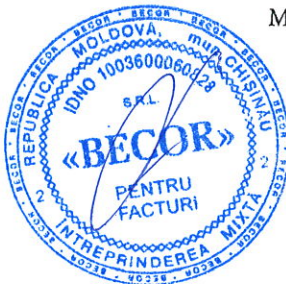
Adresse/ Address: Roche Diagnostics GmbH
Sandhofer Straße 116
D-68305 Mannheim

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

ACCU-CHEK® Active Blutglukose Überwachungssystem, bestehend aus:
ACCU-CHEK® Active blood glucose monitoring system, consisting of:

Produktname/Product name **ACCU-CHEK® Active [Model GC] mg/dL Kit 05234441**
 ACCU-CHEK® Active [Model GU] mg/dL Kit 06656897
 ACCU-CHEK® Active [Model GC] mmol/L Kit 05234450
 ACCU-CHEK® Active [Model GU] mmol/L Kit 06656919
 ACCU-CHEK® Active [Model GC] mg/dL meter only 05234476
 ACCU-CHEK® Active [Model GU] mg/dL meter only 06658008
 ACCU-CHEK® Active [Model GC] mmol/L meter only 05234468
 ACCU-CHEK® Active [Model GU] mmol/L meter only 06657982

Beschreibung/Description: Messgeräte zum Zwecke der Überwachung der
 Blutglukosekonzentration im menschlichen Blut.
 Meters for the purpose of monitoring glucose concentration in human blood.



Produktname/Product name	ACCU-CHEK® Active 05144469	(10 tests)
	ACCU-CHEK Active 06656846	(10 tests)
	ACCU-CHEK® Active 05144442	(25 tests)
	ACCU-CHEK® Active 06656803	(25 tests)
	ACCU-CHEK® Active 05144418	(50 tests)
	ACCU-CHEK® Active 06656757	(50 tests)
	ACCU-CHEK® Active 05144612	(2 x 50 tests)
	ACCU-CHEK® Active 06656854	(2 x 50 tests)
	ACCU-CHEK® Active 05144604	(12x 50 tests)
	ACCU-CHEK® Active 06887546	(12x 50 tests)

Beschreibung/Description: Teststreifen zur quantitativen Blutzuckerbestimmung mit Blutglukose Messgeräten.
Test strips for quantitative blood glucose determination with blood glucose monitors.

Produktname/Product name **ACCU-CHEK® Active Control**

Beschreibung/Description: Kontrolllösungen zur Funktionskontrolle von Blutglukose-Messgeräten und Teststreifen.
Control solutions 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, 06. June 2013

Roche Diagnostics GmbH

i.V./ On behalf of the company



Roland Hechler

Leiter OUS Regulatory Affairs
Head of OUS Regulatory Affairs

i.V./ On behalf of the company



Dr. Thomas Schmidt

Leiter Qualität Diabetes Care Systeme
Head of Quality Diabetes Care Systems



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REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Nr.	Descriere	Denum. marc.	Model	Nr. catalog	Tara	Producteur	Reprezentant	Ordin	Data
DM000005392	LANȚETE STERILE PENTRU SISTEMUL DE MONITORIZARE A GLUCOZEI DIN SÂNGE	ACCU-CHEK®	SOFTCLIX, N 25	03207492	Germania	ROCHE DIAGNOSTICS GMBH	Î.M. BECOR S.R.L.	A07/PS-01.Rg04-74	12-04-2016
DM000005886	LANȚETE STERILE PENTRU SISTEMUL DE MONITORIZARE A GLUCOZEI DIN SÂNGE	ACCU-CHEK®	SOFTCLIX, N 100	03307586	Germania	ROCHE DIAGNOSTICS GMBH	Î.M. BECOR S.R.L.	A07/PS-01.Rg04-74	12-04-2016
DM000005400	TEST PENTRU DETERMINAREA CANTITATIVĂ A GLUCOZEI DIN SÂNGE	ACCU-CHEK® ACTIVE	BANDĂ, N 10	06656846	Germania	ROCHE DIAGNOSTICS GMBH	Î.M. BECOR S.R.L.	A07/PS-01.Rg04-56	21-03-2016
DM000005401	TEST PENTRU DETERMINAREA CANTITATIVĂ A GLUCOZEI DIN SÂNGE	ACCU-CHEK® ACTIVE	BANDĂ, N 50	06656757	Germania	ROCHE DIAGNOSTICS GMBH	Î.M. BECOR S.R.L.	A07/PS-01.Rg04-56	21-03-2016
DM000004387	SISTEM PENTRU MONITORIZAREA GLUCOZEI ÎN SÂNGE	ACCU-CHEK® ACTIVE	VERSIUNEA SOFTWARE 1.0	06656919	Germania	ROCHE DIAGNOSTICS GMBH	Î.M. BECOR S.R.L.	A07/PS-01.Rg04-47	11-03-2016

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