

## 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

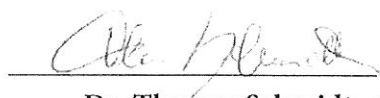
i. V./ On behalf of the company



**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

