



## APPROVAL OF CONFORMITY CERTIFICATE

**In accordance with the requirements of the In Vitro Diagnostic Directive 98/79/EC and the Medical Devices Regulations 2002:618.**

This is to certify that the Quality Management System of:

**Roche Diagnostics GmbH  
(Diabetes Care)  
Sandhofer Strasse 116  
68305 Mannheim  
Germany**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Directive 98/79/EC, and the Medical Devices Regulations 2002:618 and conforms to the requirements for the products shown below:

### **Products as listed on Certificate Schedule**

This certificate is valid only in association with the certificate schedule bearing the same number on which the products applicable to this approval are listed.

Approval is subject to the continued maintenance of the quality system in accordance with the requirements of LRQA approval 0962648/B and the requirements of the above mentioned Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Approval  
Certificate No: 0962648/D

Original Approval: 27 April 2001

LRQA Notified Body  
Registration No: 0088

Current Certificate: 1 November 2009

Certificate Expiry: 31 October 2012

Issued by: Lloyd's Register Quality Assurance Limited



## APPROVAL OF CONFORMITY CERTIFICATE SCHEDULE

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### Annex II List B products

ACCU-CHEK Compact blood glucose monitoring system, consisting of:

ACCU-CHEK Compact Plus

ACCU-CHEK Compact Plus [Model GT]

ACCU-CHEK Compact 03534634 (1 x 17 tests)

ACCU-CHEK Compact 04964489 (1 x 17 tests)

ACCU-CHEK Compact 05185262 (1 x 17 tests)

ACCU-CHEK Compact 04964519 (3 x 17 tests)

ACCU-CHEK Compact 03534642 (3 x 17 tests)

ACCU-CHEK Compact 05185289 (3 x 17 tests)

ACCU-CHEK Compact 04964527 (6 x 17 tests)

ACCU-CHEK Compact 05185297 (6 x 17 tests)

ACCU-CHEK Compact 04408101 (102 tests)

ACCU-CHEK Compact 03564126 (102 tests)

ACCU-CHEK Compact 03537323 (306 tests)

ACCU-CHEK Compact 05185319 (306 tests)

ACCU-CHEK Compact Autocontrol

ACCU-CHEK Voicemate Plus

ACCU-CHEK Voicemate Plus [Model AV]

ACCU-CHEK Active blood glucose monitoring system, consisting of:

ACCU-CHEK Active [Model GC]

ACCU-CHEK Active 03146367 (10 tests)

ACCU-CHEK Active 05144469 (10 tests)

ACCU-CHEK Active 03146359 (25 tests)

ACCU-CHEK Active 05144442 (25 tests)

ACCU-CHEK Active 03146332 (50 tests)

ACCU-CHEK Active 05144418 (50 tests)





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ACCU-CHEK Active 05144612	(2 x 50 tests)
ACCU-CHEK Active 04779223	(8 x 50 tests)
ACCU-CHEK Active 05144604	(12 x 50 tests)
ACCU-CHEK Active Control	also sold as: ACCU-CHEK Plus II Control

ACCU-CHEK Go blood glucose monitoring system, consisting of:

ACCU-CHEK Go	
ACCU-CHEK Go [Model GS]	
ACCU-CHEK Go 05183235	(10 tests)
ACCU-CHEK Go 05183090	(25 tests)
ACCU-CHEK Go 05182913	(50 tests)
ACCU-CHEK Go 05196752	(2 x 50 tests)
ACCU-CHEK Go Control	

ACCU-CHEK Integra blood glucose monitoring system, consisting of:

ACCU-CHEK Integra	
ACCU-CHEK Integra 04514769	(1 x 17 tests)
ACCU-CHEK Integra 05196434	(1 x 17 tests)
ACCU-CHEK Integra 04514696	(3 x 17 tests)
ACCU-CHEK Integra 05196507	(3 x 17 tests)

ACCU-CHEK Integra Control

ACCU-CHEK Advantage blood glucose monitoring system, consisting of:

ACCU-CHEK Advantage	also sold as: ACCU-CHEK Sensor ACCU-CHEK Comfort
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ACCU-CHEK Sensor Comfort 03374700	(10 tests)
ACCU-CHEK Sensor Comfort 03587304	(25 tests)
ACCU-CHEK Sensor Comfort 03261964	(50 tests)
ACCU-CHEK Sensor Comfort 03146146	(50 tests)
ACCU-CHEK Sensor Comfort 11895141	(50 tests)
ACCU-CHEK Sensor Comfort 03522091	(50 tests)
ACCU-CHEK Sensor Comfort 03322041	(50 tests)
ACCU-CHEK Sensor Comfort 03051170	(50 tests)
ACCU-CHEK Sensor Comfort 03374718	(50 tests)
ACCU-CHEK Sensor Comfort 04827961	(100 tests)

also sold as:

ACCU-CHEK Advantage II 03000281	(10 tests)
ACCU-CHEK Advantage II 12030535	(25 tests)
ACCU-CHEK Advantage II 12030543	(50 tests)
ACCU-CHEK Advantage II 12030659	(50 tests)
ACCU-CHEK Advantage 12030578	(50 tests)
ACCU-CHEK Advantage 12030551	(100 tests)
ACCU-CHEK Advantage Plus 04735102	(50 tests)

ACCU-CHEK Sensor Comfort Control

also sold as: ACCU-CHEK Advantage II

ACCU-CHEK Aviva blood glucose monitoring system, consisting of:  
ACCU-CHEK Aviva





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ACCU-CHEK Aviva Nano	
ACCU-CHEK Aviva Combo	
ACCU-CHEK Aviva Expert	
ACCU-CHEK Aviva 04454316	(10 tests)
ACCU-CHEK Aviva 04498062	(10 tests)
ACCU-CHEK Aviva 05225485	(10 tests)
ACCU-CHEK Aviva 04537360	(25 tests)
ACCU-CHEK Aviva 04578236	(25 tests)
ACCU-CHEK Aviva 05225493	(25 tests)
ACCU-CHEK Aviva 05589479	(30 tests)
ACCU-CHEK Aviva 04454308	(50 tests)
ACCU-CHEK Aviva 04497902	(50 tests)
ACCU-CHEK Aviva 05518008	(50 tests)
ACCU-CHEK Aviva 05225507	(50 tests)
ACCU-CHEK Aviva 05588944	(100 tests)
ACCU-CHEK Aviva 05225515	(100 tests)
ACCU-CHEK Aviva Control	

ACCU-CHEK Performa blood glucose monitoring system, consisting of:

ACCU-CHEK Performa	
ACCU-CHEK Performa Nano	
ACCU-CHEK Performa Combo	
ACCU-CHEK Performa Expert	
ACCU-CHEK Performa 04861680	(10 tests)
ACCU-CHEK Performa 05225361	(10 tests)
ACCU-CHEK Performa 04948858	(25 tests)
ACCU-CHEK Performa 05225426	(25 tests)



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### Annex II List B products (Cont.)

ACCU-CHEK Performa 04862414	(50 tests)
ACCU-CHEK Performa 05225469	(50 tests)
ACCU-CHEK Performa 04948874	(100 tests)
ACCU-CHEK Performa 05225477	(100 tests)
ACCU-CHEK Performa Control	

ACCU-CHEK Mobile blood glucose monitoring system, consisting of:

ACCU-CHEK Mobile	
ACCU-CHEK Mobile 05127670	(50 tests)
ACCU-CHEK Mobile 05190843	(2 x 50 tests)
ACCU-CHEK Mobile Control	

### Self-Test Products

Urinalysis

Ketur-Test Ketones                      also sold as: Ketur-Test Chetoni

Diabur-Test 5000 Glucose

Keto-Diabur-Test 5000 Glucose / Ketones

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