

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

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 Diabetes Care GmbH**  
**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 4009232/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: 4009232/D

Original Approval: 1 June 2015

LRQA Notified Body  
Registration No: 0088

Current Certificate: 1 November 2018

Certificate Expiry: 31 October 2021



Issued by: Lloyd's Register Quality Assurance Limited

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4009232/D SCHEDULE

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

**Roche Diabetes Care GmbH**  
**Sandhofer Strasse 116**  
**68305 Mannheim**  
**Germany**

### Annex II List B Products

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

ACCU-CHEK Compact Plus mg/dL meter only 05084270  
ACCU-CHEK Compact Plus mmol/L meter only 05084300  
ACCU-CHEK Compact Plus [Model GT] mg/dL Kit 05920051  
ACCU-CHEK Compact Plus [Model GT] mmol/L Kit 05920060  
ACCU-CHEK Compact Plus [Model GT] mg/dL Kit 05339731  
ACCU-CHEK Compact 05599423 (1 x 17 tests)  
ACCU-CHEK Compact 05599415 (3 x 17 tests)  
ACCU-CHEK Compact 05919967 (6 x 17 tests)

ACCU-CHEK Compact Plus Glucose Control 2 05888948

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

ACCU-CHEK Active [Model GU] mg/dL Kit 06656897  
ACCU-CHEK Active [Model GB] mg/dL Kit 07133766  
ACCU-CHEK Active [Model GU] mmol/L Kit 06656919  
ACCU-CHEK Active [Model GB] mmol/L Kit 07135076  
ACCU-CHEK Active [Model GB] mg/dL Set 07444141  
ACCU-CHEK Active [Model GB] mmol/L Set 07135092  
ACCU-CHEK Active [Model GU] mg/dL meter only 06658008  
ACCU-CHEK Active [Model GB] mg/dL meter only 07135114  
ACCU-CHEK Active [Model GU] mmol/L meter only 06657982  
ACCU-CHEK Active [Model GB] mmol/L meter only 07135122  
ACCU-CHEK Active 06656846 (10 tests)  
ACCU-CHEK Active 07124210 (10 tests)  
ACCU-CHEK Active 06656803 (25 tests)  
ACCU-CHEK Active 07124155 (25 tests)  
ACCU-CHEK Active 06656757 (50 tests)  
ACCU-CHEK Active 07124112 (50 tests)  
ACCU-CHEK Active 06656854 (2 x 50 tests)  
ACCU-CHEK Active 07124287 (2 x 50 tests)

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

ACCU-CHEK Active 06887546 (12 x 50 tests)  
ACCU-CHEK Active 07124279 (12 x 50 tests)  
ACCU-CHEK Active Control 03146324

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

ACCU-CHEK Guide mg/dL Kit 07400870  
ACCU-CHEK Guide mg/dL Kit 07829132  
ACCU-CHEK Guide mmol/L Kit 07400918  
ACCU-CHEK Guide mmol/L Kit 07829159  
ACCU-CHEK Guide mg/dL Set 07400926  
ACCU-CHEK Guide mmol/L Set 07400934  
ACCU-CHEK Guide mg/dL meter only 07400942  
ACCU-CHEK Guide mmol/L meter only 07400969

ACCU-CHEK Guide 07453701 (10 tests)  
ACCU-CHEK Guide 07453710 (25 tests)  
ACCU-CHEK Guide 07453728 (30 tests)  
ACCU-CHEK Guide 07453736 (50 tests)  
ACCU-CHEK Guide 07453744 (100 tests)

ACCU-CHEK Guide Controls 07748906

ACCU-CHEK Guide Link blood glucose monitoring system, consisting of:

ACCU-CHEK Guide Link mg/dL Kit 08116083  
ACCU-CHEK Guide Link mmol/L Kit 08116113

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

ACCU-CHEK Instant mg/dL Kit 07819307  
ACCU-CHEK Instant mmol/L Kit 07819315  
ACCU-CHEK Instant mg/dL Set 07819323  
ACCU-CHEK Instant mmol/L Set 07819331  
ACCU-CHEK Instant mg/dL meter only 07819340

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

ACCU-CHEK Instant mmol/L meter only 07819358

ACCU-CHEK Instant S blood glucose monitoring system, consisting of:

ACCU-CHEK Instant S mg/dL Set 07819447

ACCU-CHEK Instant S mmol/L Set 07819455

ACCU-CHEK Instant S mg/dL meter only 07819463

ACCU-CHEK Instant S mmol/L meter only 07819471

ACCU-CHEK Instant S mg/dL meter only (10 pcs) 08402698

ACCU-CHEK Instant 07819366 (10 tests)

ACCU-CHEK Instant 07819374 (25 tests)

ACCU-CHEK Instant 07869517 (30 tests)

ACCU-CHEK Instant 07819382 (50 tests)

ACCU-CHEK Instant 07819404 (100 tests)

ACCU-CHEK Instant 08474168 (6 x 50 tests)

ACCU-CHEK Instant Controls 07869525

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

ACCU-CHEK Aviva (Model NC) mg/dL meter only (5pcs) 07973748

ACCU-CHEK Aviva (Model NC) mg/dL Kit 06988563

ACCU-CHEK Aviva (Model NC) mmol/L Kit 06988709

ACCU-CHEK Aviva (Model NC) mg/dL meter only 06988601

ACCU-CHEK Aviva (Model NC) mmol/L meter only 06988610

ACCU-CHEK Aviva (Model NC) mg/dL Set 06988580

ACCU-CHEK Aviva (Model NC) mmol/L Set 06988679

ACCU-CHEK Aviva Nano mg/dL Kit 06454089

ACCU-CHEK Aviva Nano mmol/L Kit 06351646

ACCU-CHEK Aviva Nano mg/dL meter only 06454119

ACCU-CHEK Aviva Nano mmol/L meter only 06464068

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

ACCU-CHEK Aviva Nano mg/dL Kit 06647944  
ACCU-CHEK Aviva Nano mmol/L Kit 06647987  
ACCU-CHEK Aviva Combo mg/dL Set 05075645  
ACCU-CHEK Aviva Combo mg/dL Set 05075726  
ACCU-CHEK Aviva Combo mg/dL Set 05151937  
ACCU-CHEK Aviva Combo mmol/L Set 05075700  
ACCU-CHEK Aviva Combo mmol/L Set 05075718  
ACCU-CHEK Aviva Combo mmol/L Set 05172594  
ACCU-CHEK Aviva Combo mg/dL Replacement Kit - 05391555  
ACCU-CHEK Aviva Combo mg/dL Replacement Kit - 07024134  
ACCU-CHEK Aviva Combo mg/dL Replacement Kit - 05458382  
ACCU-CHEK Aviva Combo mg/dL Replacement Kit - 05458412  
ACCU-CHEK Aviva Combo mmol/L Replacement Kit - 05354978  
ACCU-CHEK Aviva Combo mg/dL Replacement Kit - 05458412  
ACCU-CHEK Aviva Combo mmol/L Replacement Kit - 05354978  
ACCU-CHEK Aviva Combo mmol/L Replacement Kit - 07024142  
ACCU-CHEK Aviva Combo mmol/L Replacement Kit - 05391563  
ACCU-CHEK Aviva Combo mmol/L Replacement Kit - 05458439  
ACCU-CHEK Aviva Expert mg/dL Set 06699430  
ACCU-CHEK Aviva Expert mg/dL Set 07227540  
ACCU-CHEK Aviva Expert mg/dL Set 08121907  
ACCU-CHEK Aviva Expert mmol/L Set 07227558  
ACCU-CHEK Aviva Expert mmol/L Set 08121893  
ACCU-CHEK Aviva Connect mg/dL Kit 07049692  
ACCU-CHEK Aviva Connect mmol/L Kit 07049889  
ACCU-CHEK Aviva Connect mg/dL Set 07049706  
ACCU-CHEK Aviva Connect mmol/L Set 07049897  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 08129479  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07163002  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07163029

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

ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07300271  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251033  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251548  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07302088  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07275331  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07251572  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251912  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251939  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07252889  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07253770  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07275331  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07251572  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251912  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07251939  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07252889  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07253770  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07249250  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07249098  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07249322  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07260881  
ACCU-CHEK Aviva Insight Meter Kit mg/dL - 07276958  
ACCU-CHEK Aviva Insight Meter Kit mmol/L - 07254318  
ACCU-CHEK Aviva Insight Meter mmol/L Replacement Kit - 07251521  
ACCU-CHEK Aviva Insight Meter mmol/L Replacement Kit - 07249241  
ACCU-CHEK Aviva Insight Meter mg/dL Replacement Kit - 07275307  
ACCU-CHEK Aviva Insight Meter mg/dL Replacement Kit - 07275323  
ACCU-CHEK Aviva Insight Meter mg/dL Replacement Kit - 07249284  
ACCU-CHEK Aviva Insight Meter mmol/L Replacement Kit - 07300336  
ACCU-CHEK Aviva Insight Meter mg/dL Replacement Kit - 07293976

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

ACCU-CHEK Aviva 06453953	(10 tests)
ACCU-CHEK Aviva 06453961	(25 tests)
ACCU-CHEK Aviva 06464211	(30 tests)
ACCU-CHEK Aviva 06453970	(50 tests)
ACCU-CHEK Aviva 06500986	(50 tests)
ACCU-CHEK Aviva 06453988	(100 tests)
ACCU-CHEK Aviva Control 04455215	
ACCU-CHEK Performa blood glucose monitoring system, consisting of:	
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 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 mg/dL meter only 05894972	
ACCU-CHEK Performa mmol/L meter only 05894999	
ACCU-CHEK Performa Combo mg/dL Replacement Kit - 05459001	
ACCU-CHEK Performa Combo mg/dL Replacement Kit - 05520959	

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

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  
ACCU-CHEK Performa Combo mmol/L Replacement Kit - 05899311  
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 06453996 (10 tests)  
ACCU-CHEK Performa 06454003 (25 tests)  
ACCU-CHEK Performa 06454011 (50 tests)  
ACCU-CHEK Performa 06454038 (100 tests)  
ACCU-CHEK Inform II 05942861 (50 tests)  
ACCU-CHEK Performa Control 04861736  
ACCU-CHEK Performa Control 05078164  
ACCU-CHEK Performa Control 05128030



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

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

ACCU-CHEK Mobile Model U1 mg/dL Kit 06383599

ACCU-CHEK Mobile Model U1 mmol/L Kit 06383602

ACCU-CHEK Mobile Model U1 mmol/L Kit (Retail) 06383645

ACCU-CHEK Mobile Model U1 mg/dL Kit (Retail) 06383629

ACCU-CHEK Mobile Model U1 mmol/L meter only 08323534

ACCU-CHEK Mobile 07141262 (25 tests)

ACCU-CHEK Mobile 05953740 (50 tests)

ACCU-CHEK Mobile 07141254 (50 tests)

ACCU-CHEK Mobile 05953758 (2 x 50 tests)

ACCU-CHEK Mobile 07203233 (2 x 50 tests)

ACCU-CHEK Mobile Control 05191165

Approval  
Certificate No: 4009232/D

Original Approval: 1 June 2015

LRQA Notified Body  
Registration No: 0088

Current Certificate: 1 November 2018

Certificate Expiry: 31 October 2021