

### 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

LRQA Notified Body Registration No: 0088 Original Approval: 1 June 2015 Current Certificate: 1 November 2018

Certificate Expiry:

~:2

31 October 2021

Issued by: Lloyd's Register Quality Assurance Limited

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

Annex II List B Products (Cont.) ACCU-CHEK Active 06887546 ACCU-CHEK Active 07124279 ACCU-CHEK Active Control 03146324

(12 x 50 tests) (12 x 50 tests)

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 tes	sts)
ACCU-CHEK Guide 07453710 (25 tes	sts)
ACCU-CHEK Guide 07453728 (30 tes	sts)
ACCU-CHEK Guide 07453736 (50 tes	sts)
ACCU-CHEK Guide 07453744 (100 to	ests)

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

(10 tests)

(25 tests)

(30 tests)

(50 tests)

(100 tests)

(6 x 50 tests)

<u>Annex II List B Products (Cont.)</u> 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 ACCU-CHEK Instant 07819374 ACCU-CHEK Instant 07869517 ACCU-CHEK Instant 07819382 ACCU-CHEK Instant 07819404 ACCU-CHEK Instant 08474168

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) mg/dL Set 06988580 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 mg/dL Kit 06351646 ACCU-CHEK Aviva Nano mg/dL meter only 06454119 ACCU-CHEK Aviva Nano mmol/L meter only 06464068

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

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 ma/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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#### Roche Diabetes Care GmbH Sandhofer Strasse 116 68305 Mannheim Germany

Annex II List B Products (Cont.)

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

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

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

#### 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 LRQA Notified Body Registration No: 0088	Original Approval:	1 June 2015
	Current Certificate:	1 November 2018
	Certificate Expiry:	31 October 2021

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