

EG-Konformitätserklärung / EC Declaration of Conformity

Hersteller / Manufacturer: Roche Diabetes Care GmbH

Adresse / Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Roche Diabetes Care GmbH erklärt unter seiner alleinigen Verantwortung, dass das Produkt / die Produktfamilie

Roche Diabetes Care GmbH declares under its sole responsibility that the product / family of products

Produktname / Product name: **Accu-Chek® Insight Insulin Pump**

Beschreibung / Description:

Kleine, tragbare, batteriebetriebene, ambulante, programmierbare und mikroprozessorgesteuerte externe Insulin-Infusions-Pumpe mit Bluetooth-Schnittstelle zur Verwendung mit einer Fernbedienung (als optionales Zubehör) für kontinuierliche, subkutane Infusion von U 100 Insulin mit variablen Basalraten.

Small, durable, battery powered, ambulatory, programmable and microprocessor controlled external insulin pump with Blue-tooth interface for use with a remote control (as an optional accessory) for continuous subcutaneous infusion of U 100 insulin with variable basal rates.

auf das / die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte in ihrer jeweils gültigen Fassung entspricht; gemäß Anhang II der Richtlinie als Konformitätsbewertungsverfahren unter Beteiligung der Benannten Stelle TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München mit der Nummer 0123 angewandt.

to which this declaration relates, complies with the EC Directive 93/42/EEC of June 14, 1993 on medical devices, as amended, using Annex II as the conformity assessment procedure with the involvement of TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München (NB 0123) as the Notified Body was followed.

Die oben aufgeführten Medizinprodukte sind gemäß Artikel 9 der EG-Richtlinie 93/42/EWG als Medizinprodukte der Klasse IIb klassifiziert.

The above mentioned medical devices are classified according Article 9 of the EC Directive 93/42/EEC as Class IIb Medical Devices.

Diese EG Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 29. März 2019 in Verkehr gebracht werden bis zur Ausstellung einer revidierten EG-Konformitätserklärung nach Änderung des Produktes und/oder durch das Ablaufdatum der von der Benannten Stelle ausgestellten Bescheinigung(en).

This EC Declaration of Conformity is valid for all the above mentioned products placed on the market beginning of 29. March 2019 and limited by the issuing of a revised declaration of conformity after change of the product and/or by the expiration date of the certificate(s) issued by the notified body.

Kontaktadresse / Contact address:

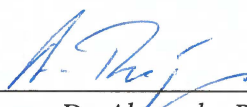
Roche Diabetes Care GmbH
Abt. Qualitätsmanagement
Sandhofer Strasse 116
68305 Mannheim
Germany

Mannheim, 29. März 2019

Roche Diabetes Care GmbH

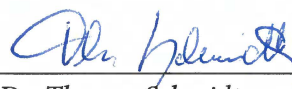
i.V./On behalf of the company

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Dr. Alexander Rügner

Leiter Regulatory Affairs Mannheim
OUS submission und IDS
Head of Regulatory Affairs Mannheim
OUS submission and IDS



Dr. Thomas Schmidt

Leiter DC Qualität Mannheim
Head of DC Quality Mannheim

Anhang / Attachment:

List of Kits/Sets that contain the Accu-Chek Insight Insulin Pump

Die in der EG-Konformitätserklärung für das Accu-Chek® Insight Insulin Pump system gelisteten Produkte werden in verschiedenen Verpackungskonfigurationen sowie in Kombination mit anderen *In-vitro*-Diagnostika und/oder Medizinprodukten von Roche Diabetes Care GmbH, als Kit oder Set bezeichnet, in den Verkehr gebracht.

The products listed in the EC Declaration of Conformity for the Accu-Chek® Insight Insulin Pump are brought to the market in several package configurations as well as in combination with other (*in vitro* diagnostic) medical devices from Roche Diabetes Care GmbH, named Kit or Set.

Die Accu-Chek® Insight Insulin Pump ist in folgenden Kits enthalten:

The Accu-Chek® Insight insulin pump is packed into the following kits:

Accu-Chek Insight Diabetes Therapy System Kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
07050828	Accu-Chek Insight system, Kit A/mmol UK/en	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set
07035799	Accu-Chek Insight system, Kit A/mg IT/it	
07292104	Accu-Chek Insight system, Kit A/mmol CH/de	
07250339	Accu-Chek Insight system, Kit A/mmol CH/fr	
07251041	Accu-Chek Insight system, Kit A/mmol CH/it	
07294301	Accu-Chek Insight system, Kit A/mg BE/de	
07276966	Accu-Chek Insight system, Kit A/mg BE/fr	
07251556	Accu-Chek Insight system, Kit A/mg BE/nl	
07251637	Accu-Chek Insight system, Kit A/mmol NL/nl	
07249365	Accu-Chek Insight system, Kit A/mmol DK/da	
07249225	Accu-Chek Insight system, Kit A/mmol SE/sv	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets)
07251955	Accu-Chek Insight system, Kit A/mmol FI/fi	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set
07251971	Accu-Chek Insight system, Kit A/mmol/ DE/de	
07252927	Accu-Chek Insight system, Kit A/mg DE/de	
07249268	Accu-Chek Insight system, Kit A/mg ES/es	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set 05511097001 Accu-Chek LinkAssist Plus
07260873	Accu-Chek Insight system, Kit A/mmol NO/no	

EG-Konformitätserklärung für / EC Declaration of Conformity for
Accu-Chek® Insight Insulin Pump

07254326	Accu-Chek Insight system, Kit A/mg PT/pt	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set 05511097001 Accu-Chek LinkAssist Plus
08157898	Accu-Chek Insight system, Kit A/mmol SL/sl	06764991001 Insight Insulin Pump 06584667001 Accu-Chek Aviva Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set
07026064	Accu-Chek Insight system, Kit P/mg AT/de	06764991001 Insight Insulin Pump 06584675001 Accu-Chek Performa Insight 06478026001 Accu-Chek Insight Flex Infusion Set
07038607	Accu-Chek Insight system, Kit P/mg FR/fr	06764991001 Insight Insulin Pump
07253800	Accu-Chek Insight system, Kit P/mmol CZ/cs	06584675001 Accu-Chek Performa Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set
07253826	Accu-Chek Insight system, Kit P/mmol SK/sk	06764991001 Insight Insulin Pump 06584675001 Accu-Chek Performa Insight 06435785001 Accu-Chek Fastclix Lancing Device 06436072001 Accu-Chek Fastclix (6 Lancets) 06478026001 Accu-Chek Insight Flex Infusion Set

Accu-Chek Insight Insulin Pump Kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
07249233	Accu-Chek Insight insulin pump, Kit sv	06764991001 Insight Insulin Pump
07008929	Accu-Chek Insight insulin pump, Kit en	
07163932	Accu-Chek Insight insulin pump, Kit it	
07038496	Accu-Chek Insight insulin pump, Kit fr	
07260849	Accu-Chek Insight insulin pump, Kit nl	
07260857	Accu-Chek Insight insulin pump, Kit da	
07260806	Accu-Chek Insight insulin pump, Kit sk	
07249217	Accu-Chek Insight insulin pump, Kit pt	
07260814	Accu-Chek Insight insulin pump, Kit cs	
07249276	Accu-Chek Insight insulin pump, Kit es	
07254296	Accu-Chek Insight insulin pump, Kit no	
07260822	Accu-Chek Insight insulin pump, Kit fi	
07050879	Accu-Chek Insight insulin pump, Kit de	

EG-Konformitätserklärung für / EC Declaration of Conformity for
Accu-Chek® Insight Insulin Pump

Accu-Chek Insight Pump Kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
09029567	Accu-Chek Insight Pump Kit de	06764991001 Insight Insulin Pump
09029575	Accu-Chek Insight Pump Kit en	
09029583	Accu-Chek Insight Pump Kit it	
09029630	Accu-Chek Insight Pump Kit sk	
09029737	Accu-Chek Insight Pump Kit no	
09029664	Accu-Chek Insight Pump Kit es	
09050728	Accu-Chek Insight Pump Kit sl	
09029591	Accu-Chek Insight Pump Kit nl	
09029648	Accu-Chek Insight Pump Kit fr	
09029613	Accu-Chek Insight Pump Kit fi	
09029605	Accu-Chek Insight Pump Kit da	
09029621	Accu-Chek Insight Pump Kit cs	
09029656	Accu-Chek Insight Pump Kit sv	
09029745	Accu-Chek Insight Pump Kit pt	

Accu-Chek Insight replacement pump kits

Katalognummer Catalog number	Beschreibung Description	Materialnummer und Kitkomponenten Material number and kit components (nur / only MDs und / and IVDs)
07306458	Accu-Chek Insight insulin pump, Replacement Kit, ROW1	06764991001 Insight Insulin Pump
07312326	Accu-Chek Insight insulin pump, Replacement Kit, Scand.	
07306482	Accu-Chek Insight insulin pump, Replacement Kit, ROW2	
07306512	Accu-Chek Insight insulin pump, Replacement Kit, ROW4	