

Konformitätserklärung gemäß der Funkgeräte-Richtlinie 2014/53/EU (RED)

Declaration of Conformity in accordance to the Radio Equipment Directive 2014/53/EU
(RED)

Hersteller/ Manufacturer:

Roche Diabetes Care GmbH

Adresse/ Address:

**Roche Diabetes Care GmbH
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 mikroprozessor gesteuerte
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.

ACCU-CHEK Insight Insulin Pump

bei bestimmungsgemäßer Verwendung den grundlegenden Anforderungen und den übrigen einschlägigen Bestimmungen der Funkgeräte-Richtlinie 2014/53/EU (RED) entspricht
complies with the essential requirements and the other relevant provisions of the Radio Equipment Directive 2014/53/EU (RED), when used for its intended purpose.

Gesundheit und Sicherheit gemäß Artikel 3 (1) (a)
Health and safety requirements pursuant to Article 3(1) a)

angewendete harmonisierte Normen:
Harmonised standards applied:

EN 60950-1:2006	Information technology equipment –Safety – Part 1:
+ A11:2009 + A1:2010	General requirements
+A2:2013 + AC:2011	
+A12:2011	

EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
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ACCU-CHEK Insight Insulin Pump

Schutzanforderungen in Bezug auf die elektromagnetische Verträglichkeit (Artikel 3 (1) (b))
Protection requirements concerning electromagnetic compatibility (Article 3(1)(b))

angewendete harmonisierte Normen:

Harmonised standards applied:

EN 301 489-1:V2.2.0 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services - Part 1: Common technical requirements - Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

EN 301 489-17:V3.2.0 Electro Magnetic Compatibility (EMC) standard for radio equipment and services - Part 17: Specific conditions for Broadband Data Transmission Systems - Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

Maßnahmen zur effizienten Nutzung des Funkfrequenzspektrums, (Artikel 3 (2))
Measures for the efficient use of the radio frequency spectrum, (Article 3 (2))

angewendete (harmonisierte) Normen:

(Harmonised) standards applied:

EN 300 328:V2.1.1 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

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Seite 4 von 4
Page 4 of 4

ACCU-CHEK Insight Insulin Pump

Diese Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 12. Juni 2017 in den Verkehr gebracht werden

The EC Declaration of Conformity is valid for all above mentioned products placed on the market of 12 June 2017.

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Mannheim, June 12, 2017

Roche Diabetes Care GmbH

i.V./ On behalf of the company

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Dr. Thomas Schmidt

Leiter Qualität Diabetes Care Systeme
Head of Quality Diabetes Care Systems



Birgit Göbel

Leiter OUS Submissions Diabetes Care
Head of OUS Submissions Diabetes Care