

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 Spirit Combo Insulin Pump [Model A]

Beschreibung / **Description:**

Tragbare, batteriebetriebene Insulinpumpe mit
Bluetooth-Schnittstelle zur Verwendung mit einer
Fernbedienung (als Zubehör) für kontinuierliche
subkutane Infusion von U100-Insulin mit
variablen Basalraten für den Gebrauch von 3,15 ml
Glas- oder Kunststoff-ampullen.

Portable, battery-operated insulin pump with Bluetooth
interface for use with a remote control (as an accessory) for
continuous subcutaneous infusion of insulin U 100 with
variable basal rates for use with 3.15 ml glass or plastic
cartridges.

ACCU-CHEK Spirit Combo 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 62368-1:2014 + A11:2017	Audio/video, information and communication technology equipment Part 1: Safety – Requirements
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EN 50566:2017-10	Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body moun
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ACCU-CHEK Spirit Combo 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 Electro Magnetic 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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Diese Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 13. Februar 2018 in den Verkehr gebracht werden

The EC Declaration of Conformity is valid for all above mentioned products placed on the market of 13 February 2018.

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Mannheim, February 13, 2018

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