

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 Aviva Insight
ACCU-CHEK Performa Insight**

Beschreibung / Description: **Messgeräte zum Zwecke der Überwachung der
Blutglukosekonzentration im menschlichen Blut
mit Bluetooth-Schnittstelle zur Verwendung als
Fernbedienung für die Accu-Chek Insight Insulin
Pumpe
Meters for the purpose of monitoring glucose concentration in
human blood with Bluetooth interface for use as a remote
control for the 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.**

ACCU-CHEK Aviva Insight
ACCU-CHEK Performa Insight

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 + A11:2009 + A1:2010 +A12:2011	Information technology equipment –Safety – Part 1: General requirements
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EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
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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
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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
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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 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.

Kontaktadresse/ Contact address:

Roche Diabetes Care GmbH
Abt. Qualitätsmanagement, DCFQ
Sandhofer Straße 116
D-68305 Mannheim
Telefax: +49 621/759 3801

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 Diabestes Care Systems



Birgit Göbel

Leiter OUS Submissions Diabetes Care
Head of OUS Submissions Diabetes Care