

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

Roche Diabetes Care GmbH declares under its sole responsibility that the product

Produktname/ **Product name:**

ACCU-CHEK® Mobile Wireless Adapter

Beschreibung / **Description:**

Elektronischer USB Adapter zur Übertragung von
Glukosemesswerten von einem ACCU-CHEK®
Mobile Blutglucose Messgerät an eine Mobile
App mittels einer Bluetooth Low Energy
Verbindung.

Electronic USB adapter to transmit glucose
measurements from a ACCU-CHEK® Mobile glucose
meter to a mobile app via Bluetooth Low Energy
connection.

ACCU-CHEK® Mobile Wireless Adapter

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
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 mounted devices in close proximity to the human body

ACCU-CHEK® Mobile Wireless Adapter

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:V2.1.1 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:V3.1.1 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

ACCU-CHEK® Mobile Wireless Adapter

Diese Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 25. Juni 2018 in den Verkehr gebracht werden

The EC Declaration of Conformity is valid for all above mentioned products placed on the market of 25. June 2018.

Kontaktadresse/ Contact address:

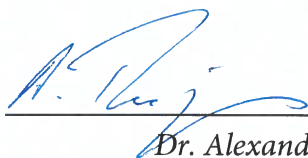
Roche Diabetes Care GmbH
Abt. Qualitätsmanagement, DCQA
Sandhofer Straße 116
D-68305 Mannheim
Telefax: +49 621/759 3801

Mannheim, *25-Jun-2018*

Roche Diabetes Care GmbH

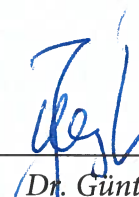
i.V. / On behalf of the company

i.V. / On behalf of the company



Dr. Alexander Rüchner

Leiter Regulatory Affairs IDS und OUS
submission *Diabetes Care*
Head of Regulatory Affairs IDS and OUS submission
Diabetes Care



Dr. Günter Jungwirt

Leiter Qualitätssicherung *Diabetes Care*
Mannheim
Head of Quality Assurance Diabetes Care Mannheim