

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 Instant

Beschreibung / **Description:**

Messgeräte zum Zwecke der Überwachung der
Blutglukosekonzentration im menschlichen Blut
Meters for the purpose of monitoring glucose concentration
in human blood

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 Instant

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

angewendete harmonisierte Normen:

Harmonised standards applied:

IEC 61010-1:2010	Information technology equipment. Safety. General
IEC 61010-1:2010/ AMD1:2016	requirements
IEC 61010-2-101:2018	
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 (10MHz to 300 GHz)

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:V2.2.3	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 1: Common technical requirements
EN 301 489-17:V3.2.4	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

ACCU-CHEK Instant

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:V2.2.2 Electromagnetic compatibility and Radio spectrum
Matters (ERM); Wideband transmission systems; Data
transmission equipment operating in the 2,4 GHz ISM
band and using wide band modulation techniques;
Harmonized EN covering essential requirements under
article 3.2 of the R&TTE Directive

Diese Konformitätserklärung ist für alle oben aufgeführten Produkte gültig, die ab dem 7.
Juli 2022 in den Verkehr gebracht werden

***The EC Declaration of Conformity is valid for all above mentioned products placed on the market of
July 7, 2022.***

Kontaktadresse/ **Contact address:**

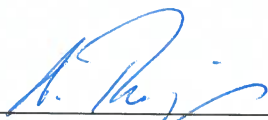
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Mannheim, July 7, 2022

Roche Diabetes Care GmbH

i.V./On behalf of the company

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Dr. Alexander Rügner

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Head of Safety Evidence Reporting and Regulatory



Dr. Thomas Schmidt

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Head of DC Quality Mannheim