EU-Konformitätserklärung - RED

EU declaration of conformity - RED

Accu-Chek® Mobile Blood Glucose Meter

Rev. 02

Hersteller
Manufacturer

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 / product family:

Produkt- und Handelsname Product and trade name	REF	Katalognummer Catalogue number	Ergänzende Information Complementary information
Accu-Chek® Mobile Blood Glucose Meter		10122412001 10193867001	mg/dL mmol/L

Roche Diabetes Care GmbH

Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 720251 - Geschäftsführung: Michael Götzl - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

EU-Konformitätserklärung (RED) für / EU declaration of conformity (RED) for
Accu-Chek® Mobile Blood Glucose Meter; Rev. 02

Produktbeschreibung:	Das Accu-Chek Mobile Blutzuckermessgerät, das mit den Accu-Chek Mobile Testkassetten zu verwenden ist, ist zur quantitativen Messung von Glukose in frischem Kapillarvollblut aus dem Finger indiziert als Hilfsmittel zur Überwachung der Wirksamkeit der Glukosekontrolle. Das Accu-Chek Mobile Blutzuckermessgerät, das mit den Accu-Chek Mobile Testkassetten zu verwenden ist, ist als In-vitro-Diagnostikum zur Selbstanwendung durch Menschen mit Diabetes vorgesehen.
Product description:	The Accu-Chek Mobile blood glucose meter with the Accu-Chek Mobile test cassettes is indicated to quantitatively measure glucose in fresh capillary whole blood from the finger as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Mobile blood glucose meter with the Accu-Chek Mobile test cassettes is intended for in vitro diagnostic self-testing by people with diabetes.

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

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

Angewandte harmonisierte Normen:
Harmonised standards applied:

EN 61010-1:2010/A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General 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 (Note: fulfilled via low power exemption using EN 62479, described in EN62209-2, Annex K.2 (EN50566 refers to EN62209-2 for testing)
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 gemäß Artikel 3 (1) b)
Protection requirements concerning electromagnetic compatibility pursuant to Article 3 (1) b)

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Angewandte harmonisierte Normen:
Harmonised standars applied:

EN 301 489-1:V2.2.0	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment; Part 1: Common technical requirements
EN 301 489-3:V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

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

Angewandte harmonisierte Normen:
Harmonised standards applied:

EN 300 330:V2.1.1	Short Range Devices (SRD) - Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz

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This EU declaration of conformity is valid for all the above mentioned products placed on the market beginning with the date of last signature performed on this document and limited by the issuing of a revised EU declaration of conformity after change of the product and/or by the expiration date of the certificate issued by the notified body.

Roche Diabetes Care GmbH

i. V. / on behalf of the company
05-Feb-2024 | 17:50 MEZ

Alexander Rügner

Dr. Alexander Rügner
Leiter Safety, Evidence Reporting und Regulatory

Head of Safety, Evidence Reporting and Regulatory

i. V. / on behalf of the company
06-Feb-2024 | 14:34 MEZ

Kai Küllmer

Dr. Kai Küllmer
Für die Einhaltung der Regulierungsvorschriften verantwortliche Person nach Art. 15 MDR/IVDR

Person responsible for regulatory compliance according to Art. 15 MDR/IVDR