EU-Konformitätserklärung - RED

EU declaration of conformity - RED

Accu-Chek® SmartGuide device

Rev. 01

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® SmartGuide device		09907050	n/a

Produktbeschreibung:	Das Gerät zur kontinuierlichen Glukoseüberwachung (CGM-Gerät) ist für die kontinuierliche Messung des Echtzeit-Glukosespiegels in der subkutanen interstitiellen Flüssigkeit bestimmt.

Roche Diabetes Care GmbH

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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® SmartGuide device*;* Rev. 01

Product description:	The continuous glucose monitoring device (CGM device) is intended for continuous measurement of real-time glucose levels in the subcutaneous interstitial fluid.

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.

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

Angewandte harmonisierte Normen:
Harmonised standards applied:

IEC 60601 -1: 2005 IEC 60601 -1: 2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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)

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Schutzanforderungen in Bezug auf die elektromagnetische Verträglichkeit gemäß Artikel 3 (1) b)
Protection requirements concerning electromagnetic compatibility pursuant to Article 3 (1) b)

Angewandte harmonisierte Normen:
Harmonised standars applied:

ETSI EN 301 489-1:V2.2.3 (2019-11)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 1: Common technical requirements
ETSI EN 301 489-17:V3.2.4 (2020-09)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

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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 standars applied:

ETSI 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

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
06-Mai-2024 | 16:19 MESZ

Alexander Rügner

Dr. Alexander Rügner
Leiter Safety, Evidence Reporting
und
Regulatory Affairs

Head of Safety, Evidence Reporting
and Regulatory

i. V. / on behalf of the company
06-Mai-2024 | 16:50 MESZ

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