



EU-Konformitätserklärung - RED

EU declaration of conformity - RED

Accu-Chek® Solo pump base

Rev. 03

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	REF	Katalognummer	Ergänzende Information
Product and trade name		Catalogue number	Complementary information
Accu-Chek® Solo pump base		07835639	EU,ROW
Accu-Chek® Solo pump base		07873972	ROW 2
Accu-Chek® Solo pump base		07857772	ROW 3
Accu-Chek® Solo pump base		09207686	ROW 4
Produktbeschreibung:	Tragbare, batteriebetriebene und schlauchlose Mikro-Insulinpumpe, die kabellos per BLE gesteuert und programmiert wird.		

EU-Konformitätserklärung (RED) für / EU declaration of conformity (RED) for
Accu-Chek® Solo pump base; Rev. 03

Product description:	Portable, battery-operated and tubeless insulin micropump steered and programmed wirelessly via BLE.
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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	Medical electrical equipment - Part 1: General requirements for basic
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IEC 60601 -1: 2005 / AMD1:2012	safety and essential performance
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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 (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 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

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 300 328: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

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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

30-Apr-2024 | 13:06 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

30-Apr-2024 | 13:16 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