ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 092547 0018 Rev. 03

Manufacturer:

Roche Diabetes Care GmbH
Sandhofer Strasse 116
68305 Mannheim
GERMANY

SRN Manufacturer: DE-MF-000006276

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 092547 0018 Rev. 03

Report No.: 713253476

Preceding Certificate No.: G10 092547 0018 Rev. 02

Valid from: 2023-02-02
Valid until: 2025-09-12

Date of Initial Issuance: 2020-10-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-02-02

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	IIa
Device Group:	V0104 - LANCETS, SINGLE-USE
Intended Purpose:	-

Classification:	IIa
Device Group:	Z120402 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS
Intended Purpose:	-

Classification:	IIb
Device Group:	Z120402 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS
Intended Purpose:	The Accu-Chek Solo Diabetes Manager is used to configure and control the micropump. The Accu-Chek Solo Diabetes Manager is needed to fulfil the intended purpose of the Accu-Chek Solo micropump. The bolus advice of the Accu-Chek Solo Diabetes Manager gives an advise for correction bolus or meal bolus. The Accu-Chek Solo Diabetes Manager includes a blood glucose monitoring System that is intended for self-testing.

Classification:	IIb
Device Group:	Z120402 - GENERAL MEDICINE THERAPEUTIC TREATMENT INSTRUMENTS
Intended Purpose:	The Accu-Chek Solo pump base is part of the micropump. It contains the mechanical parts as well as the electronics to control and monitor the operation of the pump. The Accu-Chek Solo pump base is intended for continuous insulin infusion in the treatment of diabetes mellitus requiring insulin.

Classification:	IIb
Device Group:	A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	The Accu-Chek Solo cannula assembly consists of the cannula casing and the sterile cannula. It creates a connection between the micropump and the body to channel the insulin into the body. The Accu-Chek Solo pump holder is a plate that is adhered to the skin to fix the cannula in place. It also holds the Accu-Chek Solo micropump in place.

Classification:	IIb
Device Group:	A030401 - INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	The infusion set is intended for the subcutaneous infusion of insulin delivered by an insulin pump.

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The validity of this certificate depends on conditions and/or is limited to the following: - none -

Revision History:

Rev.	Dated	Report
00	2020-10-09	713180066
01	2021-05-07	713208520
02	2021-11-16	713209526

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