



Erklärung gemäß Artikel 22 Verordnung (EU) 2017/745

Declaration according article 22 /Regulation (EU) 2017/745

Accu-Chek® Solo micropump system

Rev. 05

Roche Diabetes Care GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

Actor identification number (Actor ID)

DE-PR-000006275

System/procedure pack producer

Wir, Roche Diabetes Care GmbH erklären, dass (a) die gegenseitige Vereinbarkeit der in den untenstehenden Verpackungsvarianten enthaltenen Produkte geprüft wurde, (b) das System oder die Behandlungseinheit verpackt und mit einschlägigen Produktinformationen versehen ist, (c) die Zusammenstellung der Produkte in die Verpackungsvarianten intern überwacht, überprüft und validiert wird.

We, Roche Diabetes Care GmbH declare, that (a) the mutual compatibility of the devices within the below listed packaging configurations has been verified (b) the system or procedure pack has been packaged and supplied with relevant information (c) the activity of combining devices was subject to appropriate methods of internal monitoring, verification and validation.

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Produktinformation
 Product information

Basis UDI-DI 4015630SA0709935
 Basic UDI-DI , for Accu-Chek Solo
 system kit – Aviva

Produkt- und Handelsname	REF Katalognummer	Ergänzende Information
Product and trade name	Catalogue number	Complementary information
Accu-Chek® Solo micropump system	07864183001	A mol SE/sv
Accu-Chek® Solo micropump system	07864175001	A mol FI/fi
Accu-Chek® Solo micropump system	07864213001	A mg IT/it
Accu-Chek® Solo micropump system	07864205001	A mg ES/es

Die oben genannten Verpackungskonfigurationen werden aus untenstehenden
 Medizinprodukte mit den jeweilig zugeordneten Basis-UDI-DI zusammengestellt:
 Above mentioned packaging configurations are comprised of several of the below medical
 devices with the assigned Basic-UDI-DI:

Produkt- und Handelsname	Basis-UDI-DI
Product and trade name	Basic UDI-DI
Accu-Chek® Solo pump base	4015630PB07099ZU
Accu-Chek® Solo insertion device	4015630ID07099WX
Accu-Chek® Aviva Solo diabetes manager	4015630DA07099T3

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Basis UDI-DI 4015630SG070995K
 Basic UDI-DI , for Accu-Chek Solo
 system kit - Guide

Produkt- und Handelsname	REF Katalognummer	Ergänzende Information
Product and trade name	Catalogue number	Complementary information
Accu-Chek® Solo micropump system	09284494001	G mg IT/it
Accu-Chek® Solo micropump system	09265422001	G mg FR/fr
Accu-Chek® Solo micropump system	09265503001	G mg SA/ar
Accu-Chek® Solo micropump system	09887288001	G mg GR/el
Accu-Chek® Solo micropump system	09888128001	G mg IL/he
Accu-Chek® Solo micropump system	09773061001	G mg BE/nl
Accu-Chek® Solo micropump system	09773070001	G mg BE/fr
Accu-Chek® Solo micropump system	09773088001	G mg BE/de
Accu-Chek® Solo micropump system	09265465001	G mol NL/nl
Accu-Chek® Solo micropump system	09265490001	G mol HU/hu
Accu-Chek® Solo micropump system	09284010001	G mol UK/en
Accu-Chek® Solo micropump system	09888187001	G mol CH/it
Accu-Chek® Solo micropump system	09888144001	G mol CH/de
Accu-Chek® Solo micropump system	09888179001	G mol CH/fr
Accu-Chek® Solo micropump system	09772588001	G mol CZ/cs
Accu-Chek® Solo micropump system	09385673001	G mg ROW/es
Accu-Chek® Solo micropump system	09770291001	G mg TW/zht
Accu-Chek® Solo micropump system	09767282001	G mg BR/ptb
Accu-Chek® Solo micropump system	09433759001	G mol RU/ru
Accu-Chek® Solo micropump system	09524231001	G mg DE/de
Accu-Chek® Solo micropump system	09524215001	G mol DE/de
Accu-Chek® Solo micropump system	09524223001	G mol AU/en
Accu-Chek® Solo micropump system	09448802001	G mg ES/es
Accu-Chek® Solo micropump system	09817689001	G mg PT/pt
Accu-Chek® Solo micropump system	09983848001	G mg BR/ptb
Accu-Chek® Solo micropump system	08874042001	G mg JP/ja
Accu-Chek® Solo micropump system	09433830001	G mol DK/da
Accu-Chek® Solo micropump system	09433856001	G mol FI/fi
Accu-Chek® Solo micropump system	09433821001	G mol NO/no
Accu-Chek® Solo micropump system	09433848001	G mol SE/sv

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Accu-Chek® Solo micropump system

09433791001

G mg PL/pl

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Medizinprodukten mit den jeweilig zugeordneten Basis-UDI-DI zusammengestellt:
Above mentioned packaging configurations are comprised of several of the below medical
devices with the assigned Basic-UDI-DI:

Produkt- und Handelsname Product and trade name	Basis-UDI-DI Basic UDI-DI
Accu-Chek® Solo pump base	4015630PB07099ZU
Accu-Chek® Solo insertion device	4015630ID07099WX
Accu-Chek® Guide Solo diabetes manager	4015630DG07099VH

Roche Diabetes Care GmbH Mannheim

i. V. / on behalf of the company

16-okt-2023

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

18-okt-2023

Kai Küllmer

Dr. Kai Küllmer

Für die Einhaltung der
Regulierungsvorschriften
verantwortliche Person nach Art. 15
MDR

Person responsible for regulatory
compliance according to Art. 15 MDR