



Erklärung gemäß Artikel 22 Verordnung (EU) 2017/745

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

Accu-Chek® Instant Kit

Rev. 01

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.

Erklärung gemäß Artikel 22 Verordnung (EU) 2017/745
 Declaration according article 22 Regulation (EU) 2017/745
 Accu-Chek® Instant Kit; Rev. 01

Produktinformation
 Product information

Basis UDI-DI
 Basic UDI-DI , 4015630KS1010849

| Produkt- und Handelsname Product and trade name | REF | Katalognummer Catalogue number | Ergänzende Information Complementary information |
|----------------------------------------------------|------------|-----------------------------------|-----------------------------------------------------|
| Accu-Chek® Instant Kit | | 09221786003 | mmol/L, SC |
| Accu-Chek® Instant Kit | | 09221786015 | mmol/L, SC |
| Accu-Chek® Instant Kit | | 09221786340 | mmol/L, SC |
| Accu-Chek® Instant Kit | | 09221786345 | mmol/L, SC |
| Accu-Chek® Instant Kit | | 09292004003 | mmol/L, SC, FOC |

Basis UDI-DI
 Basic UDI-DI , 4015630KS1010849

| Produkt- und Handelsname Product and trade name | REF | Katalognummer Catalogue number | Ergänzende Information Complementary information |
|----------------------------------------------------|------------|-----------------------------------|-----------------------------------------------------|
| Accu-Chek® Instant Kit | | 09221794003 | mg/dL, SC |
| Accu-Chek® Instant Kit | | 09221794023 | mg/dL, SC, LA/APAC |
| Accu-Chek® Instant Kit | | 09221794050 | mg/dL, SC |
| Accu-Chek® Instant Kit | | 09221794078 | mg/dL, SC |
| Accu-Chek® Instant Kit | | 09291911003 | mg/dL, SC, FOC |

Basis UDI-DI
 Basic UDI-DI , 4015630KF10108WV

| Produkt- und Handelsname Product and trade name | REF | Katalognummer Catalogue number | Ergänzende Information Complementary information |
|----------------------------------------------------|------------|-----------------------------------|-----------------------------------------------------|
| Accu-Chek® Instant Kit | | 09221786005 | mmol/L, FC |
| Accu-Chek® Instant Kit | | 09221786018 | mmol/L, FC |
| Accu-Chek® Instant Kit | | 09221786041 | mmol/L, FC |
| Accu-Chek® Instant Kit | | 09221794005 | mg/dL, FC |
| Accu-Chek® Instant Kit | | 09221794049 | mg/dL, FC |

Erklärung gemäß Artikel 22 Verordnung (EU) 2017/745
Declaration according article 22 Regulation (EU) 2017/745
Accu-Chek® Instant Kit; Rev. 01

Die oben genannten Verpackungskonfigurationen werden aus untenstehenden 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 Instant Meter | 4015630GM10108XL |
| Accu-Chek Instant Strips | 4015630ST09331AP |
| Accu-Chek Softclix lancets | 4015630LC06715XZ |
| Accu-Chek Softclix Lancing device | 4015630LD06715YE |
| Accu-Chek® Fastclix lancet drum | 4015630LC06716Y3 |
| Accu-Chek® Fastclix Lancing device | 4015630LD09225YD |

Roche Diabetes Care GmbH

i. V. / on behalf of the company

14-Mai-2024 | 15:37 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

14-Mai-2024 | 17:04 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