



# EU Declaration of Conformity

Accu-Chek® Instant Control

Rev. 01

Manufacturer



Roche Diabetes Care GmbH

Sandhofer Strasse 116

68305 Mannheim

Germany

Single Registration Number (SRN)

DE-MF-000006276

Roche Diabetes Care GmbH declares under its sole responsibility, that the product

Produktinformation

Product information

Basic UDI-DI

4015630CL09333WY

Produkt- und Handelsname



Katalognummer

Ergänzende Information

Product and trade name

Catalogue number

Complementary information

Accu-Chek® Instant Control

07869525

n/a

Roche Diabetes Care GmbH

Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 720251 - Geschäftsführung: Michael Götzl -  
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

EU declaration of conformity for  
Accu-Chek® Instant Control, Rev 01

---

Zweckbestimmung:

Die Accu-Chek Instant Kontrolllösung ist für die Funktionskontrolle von Accu-Chek Instant Blutzuckermessgeräten und Accu-Chek Instant Teststreifen vorgesehen. Das Produkt ist zur Eigenanwendung durch Menschen mit Diabetes sowie für patientennahe Tests durch medizinisches Fachpersonal vorgesehen.

Intended Purpose:

The Accu-Chek Instant control solution is intended for performing control tests on Accu-Chek Instant and Accu-Chek Instant S blood glucose meters and Accu-Chek Instant test strips. It is intended for self-testing by people with diabetes and for near-patient testing by healthcare professionals.

---

Risk Class

A B C D

---

Conformity Route

Self-Declaration of Conformity (Class A)  
 Technical Documentation Assessment – Annex IX

---

Certificates

EU QM Certificate  
No.: V10 092547 0022  
 EU Technical Documentation Assessment Certificate  
No. V74 092547 0029

---

Other

Common Specifications:

---

Notified Body (NB)

TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München

---

NB Ident. No.

0123

---

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

EU declaration of conformity for  
Accu-Chek® Instant Control, Rev 01

Roche Diabetes Care GmbH Mannheim

i. V. / on behalf of the company  
03-Mai-2024 | 13:35 MESZ

*Alexander Rügner*

---

Dr. Alexander Rügner

Head of Safety, Evidence Reporting and  
Regulatory  
Head of Safety, Evidence Reporting and  
Regulatory

i. V. / on behalf of the company  
03-Mai-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