



EU Declaration of Conformity

Accu-Chek® Guide 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

Product information

Basic UDI-DI

4015630CT093502B

Produkt- und Handelsname



Katalognummer Ergänzende Information

Product and trade name

Catalogue number Complementary information

Accu-Chek® Guide Control

07748906

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

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Accu-Chek® Guide Control, Rev 01

Zweckbestimmung:

Intended Purpose:

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

The Accu-Chek Guide control solution is intended for performing control tests on the Accu-Chek Guide family of blood glucose meters and the Accu-Chek Guide 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 0028

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.

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Roche Diabetes Care GmbH Mannheim

i. V. / on behalf of the company

11-Apr-2024 | 18:43 MESZ

Alexander Rügner

Dr. Alexander Rügner

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

i. V. / on behalf of the company

12-Apr-2024 | 09:25 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