



EU Declaration of Conformity

Accu-Chek® Linearity Test Kit

Rev. 02

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,

4015630CL06695XG

Produkt- und Handelsname

Katalognummer

Ergänzende Information

Product and trade name

Catalogue number

Complementary
information

Accu-Chek® Linearity Test Kit

05048010

Intended Purpose:

The linearity solution is intended for performing linearity tests on the dedicated test strips and blood glucose meters. It is indicated for near-patient testing by healthcare professionals. Use only for periodic verification of linearity of Accu-Chek systems using Accu-Chek Aviva, Accu-Chek Performa and Accu-Chek Inform II test strips.

Risk Class

A B C D

Roche Diabetes Care GmbH

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

EU declaration of conformity for
Accu-Chek® Linearity Test Kit, Rev. 02

Conformity Route	<input type="checkbox"/> Self-Declaration of Conformity (Class A) <input checked="" type="checkbox"/> Technical Documentation Assessment – Annex IX
Certificates	<input checked="" type="checkbox"/> EU QM Certificate No.: V10 092547 0022 <input checked="" type="checkbox"/> EU Technical Documentation Assessment Certificate No. V74 092547 0026
Other	<input type="checkbox"/> 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.

Roche Diabetes Care GmbH

i. V. / on behalf of the company

12-Feb-2024 | 18:10 MEZ

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

12-Feb-2024 | 18:41 MEZ

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