



EU Declaration of Conformity

Accu-Chek® Instant Linearity Kit

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 ,

4015630LY102687X

Produkt- und Handelsname



Katalognummer Ergänzende Information

Product and trade name

Catalogue number Complementary information

Accu-Chek® Instant Linearity Kit

07869622

n/a

Zweckbestimmung:

Intended Purpose:

Siehe Intended Purpose

The Accu-Chek Instant linearity test kit is intended for periodic verification of linearity of the Accu-Chek Instant and Accu-Chek Instant S systems using Accu-Chek Instant test strips. It is intended for near-patient testing by healthcare professionals only.

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 Linearity Kit, Rev 01

Risk Class	<input type="checkbox"/> A <input type="checkbox"/> B <input checked="" type="checkbox"/> C <input type="checkbox"/> D
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 0029
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 Mannheim

i. V. / on behalf of the company
03-Mai-2024 | 13:34 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 | 13:34 MESZ

Kai Küllmer

Dr. Kai Küllmer

Für die Einhaltung der Regulierungs-
vorschriften verantwortliche Person
nach Art. 15 MDR/IVDR
Person Responsible for Regulatory
Compliance according to Art. 15
MDR/IVDR