EU Declaration of Conformity

Accu-Chek® Guide 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 ,		4015630LK093503F	
Produkt- und Handelsname Product and trade name	REF	Katalognummer Catalogue number	Ergänzende Information Complementary information
Accu-Chek® Guide Linearity Kit		07748973	---

Zweckbestimmung:	Intended Purpose:
Das Accu-Chek Guide Linearitätstestkit ist für die periodische Linearitätsprüfung der Accu-Chek Guide Produktfamilie unter Verwendung der Accu-Chek Guide Teststreifen vorgesehen. Es ist ausschließlich für patientennahe Tests durch medizinisches Fachpersonal vorgesehen.	The Accu-Chek Guide linearity test kit is intended for periodic verification of linearity of the Accu-Chek Guide family of meters using the Accu-Chek Guide test strips. It is intended for near-patient testing by healthcare professionals only.

EU declaration of conformity for
Accu-Chek® Guide Linearity Kit, Rev 01

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.

Roche Diabetes Care GmbH Mannheim

i. V. / on behalf of the company
12-Apr-2024 | 15:32 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
16-Apr-2024 | 14:17 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