

EU Declaration of Conformity

Accu-Chek® Linearity Test 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

4015630CL06695XG

Product and trade name

Accu-Chek® Linearity Test Kit



Catalogue number

05048010

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 0026

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

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Accu-Chek® Linearity Test Kit Rev. 01

Mannheim, 08. Jul. 2022
Roche Diabetes Care GmbH

i.V./on behalf of the company



Dr. Alexander Rügner

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

i.V./on behalf of the company



Dr. Thomas Schmidt

Leiter DC Qualität Mannheim
Head of DC Quality Mannheim

Attachment:

List of components and Kits/Sets of the Accu-Chek® Linearity Test Kit

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The products listed in the EU declaration of conformity for the Accu-Chek® Linearity Test Kit are packed into several package configurations as bulk device, see list below

Product and trade name	Catalogue number
N/A	N/A