

EU Declaration of Conformity

Accu-Chek® Active 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

4015630CL02010UL

Product and trade name

Accu-Chek® Active Control



Catalogue number

03146324

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 Rev.00

EU Technical Documentation Assessment Certificate

No.: V74 092547 0023 Rev. 00

Other

Common Specifications:

Notified Body (NB)

TÜV SÜD Product Service GmbH

Ridlerstraße 65

80339 München

NB Ident. No.

0123

Roche Diabetes Care GmbH

Sandhofer Straße 116
68305 Mannheim

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: Alexander Moser - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

EU declaration of conformity for
Accu-Chek® Active Control Rev. 01

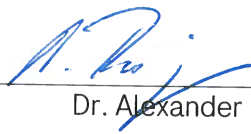
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices as well as Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Mannheim, 7 April 2022

Roche Diabetes Care GmbH

i.V./on behalf of the company

i.V./on behalf of the company



Dr. Alexander Rügner

Leiter Safety, Evidence, Reporting & Regulatory
Safety, Evidence, Reporting & Regulatory Chapter Lead



Dr. Thomas Schmidt

Leiter DC Qualität Mannheim
Head of DC Quality Mannheim

Attachment:

List of components and Kits/Sets of the Accu-Chek® Active Control

EU declaration of conformity for
Accu-Chek® Active Control Rev. 01

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

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