

## EU Declaration of Conformity

Accu-Chek® Active Strips

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**

**4015630ST020108F**

**Product and trade name**

**REF**

**Catalogue number**

Accu-Chek® Active strips 50 tests

07124112

Accu-Chek® Active strips 25 tests

07124155

Accu-Chek® Active strips 10 tests

07124210

Accu-Chek® Active strips 12 x 50 tests

07124279

Accu-Chek® Active strips 2 x 50 tests

07124287

**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

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

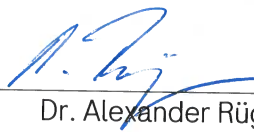
EU declaration of conformity for  
Accu-Chek® Active Strips Rev. 01

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



Dr. Alexander Rügner

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

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® Active Strips

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

<b>Product and trade name</b>	Catalogue number
<b>n.a.</b>	<b>n.a.</b>