

## **EC Declaration of Conformity**

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

### **Accu-Chek Active Strips**

Rev.01

**Manufacturer:** Roche Diabetes Care GmbH  
**Address:** Sandhofer Strasse 116  
68305 Mannheim  
Germany

**Single Registration** DE-MF-000006276  
**Number:**

**Roche Diabetes Care GmbH declares, under the sole responsibility, that the product/the product line**

<b><i>Product and trade name</i></b>	<b><i>Catalogue number</i></b>
<i>Accu-Chek® Active strips 50 tests</i>	<i>07124112</i>
<i>Accu-Chek® Active strips 25 tests</i>	<i>07124155</i>
<i>Accu-Chek® Active strips 10 tests</i>	<i>07124210</i>
<i>Accu-Chek® Active strips 12 x 50 tests</i>	<i>07124279</i>
<i>Accu-Chek® Active strips 2 x 50 tests</i>	<i>07124287</i>

***Basic UDI-DI:*** 4015630ST020108F

***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) Name:*** TÜV Süd Product Service GmbH  
***NB Address:*** Ridlerstraße 65  
80339 Munich  
Germany  
***NB Ident. No.:*** 0123

**EC Declaration of Conformity**  
Accu-Chek Active Strips



*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, November 8, 2021

Roche Diabetes Care GmbH

i.V./on behalf of the company

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A blue ink signature of Dr. Alexander Rügner, written in a cursive style, positioned above a horizontal line.

*Dr. Alexander Rügner*

Leiter Regulatory Affairs Mannheim  
OUS submissions und IDS  
Head of Regulatory Affairs Mannheim  
OUS submissions and IDS

A blue ink signature of Dr. Thomas Schmidt, written in a cursive style, positioned above a horizontal line.

*Dr. Thomas Schmidt*

Leiter DC Qualität Mannheim  
Head of DC Quality Mannheim