

## EU Declaration of Conformity

Accu-Chek® Aviva Control

Rev. 01

### Manufacturer



**Roche Diabetes Care GmbH**

Sandhofer Strasse 116  
68305 Mannheim  
Germany

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### Single Registration Number (SRN)

DE-MF-000006276

Roche Diabetes Care GmbH declares under its sole responsibility, that the product

### Product information

#### Basic UDI-DI

4015630CL02012UQ

#### Product and trade name

Accu-Chek® Aviva Control



#### Catalogue number

04455215

#### 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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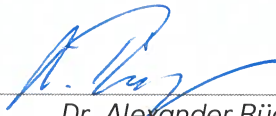
Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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

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Mannheim, 08. Jul. 2022  
Roche Diabetes Care GmbH

i.V./on behalf of the company



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Dr. Alexander Rügner

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

i.V./on behalf of the company



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Dr. Thomas Schmidt

Leiter DC Qualität Mannheim  
**Head of DC Quality Mannheim**

**Attachment:**

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

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

| <b>Product and trade name</b> | <b>Catalogue number</b> |
|-------------------------------|-------------------------|
| N/A                           | N/A                     |