

EU Declaration of Conformity

Accu-Chek® Performa 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

4015630CL02363VQ

Product and trade name



Catalogue number

Accu-Chek® Performa Control

04861736

Accu-Chek® Performa Control

05078164

Accu-Chek® Performa Control

05128030

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

Roche Diabetes Care GmbH

Sandhofer Straße 116
68305 Mannheim

Roche Diabetes Care GmbH

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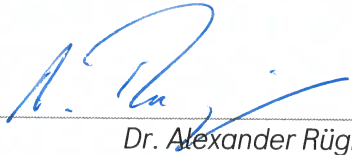
Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 720251 - Geschäftsführung: Alexander Moser - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro
diagnostic medical devices.

Mannheim, 08. Jul. 2022
Roche Diabetes Care GmbH

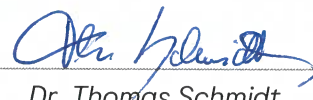
i.V./on behalf of the company



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® Performa Control

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

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