

EU Declaration of Conformity

Accu-Chek® Performa 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 ,

4015630ST023639K

Product and trade name

REF

Catalogue number

Accu-Chek® Performa Strips 10 tests

06453996

Accu-Chek® Performa Strips 10 tests

08966648

Accu-Chek® Performa Strips 10 tests

09049851

Accu-Chek® Performa Strips 25 tests

06454003

Accu-Chek® Performa Strips 50 tests

06454011

Accu-Chek® Performa Strips 100 tests

06454038

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:

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® Performa Strips Rev. 01

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.

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 Strips

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

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