EU Declaration of Conformity

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

Manufacturer:	Roche Diabetes Care GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-MF-000006276

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

Product Name	Cat. No. / REF	Basic UDI-DI
Accu-Chek® Instant Meter	09221832 mg/dL	4015630GM10108XL
Accu-Chek® Instant Meter	09221824 mmol/L	4015630GM10108XL

Intended Purpose:

The Accu-Chek Instant meter with the Accu-Chek Instant test strips is indicated to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control.
The Accu-Chek Instant meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic self-testing by people with diabetes.
The Accu-Chek Instant meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic near-patient testing by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

Risk Class: ☐ A ☐ B ☒ C ☐ D

Conformity Route:

☐ Self-Declaration of Conformity (Class A)
☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
☒ Technical Documentation Assessment Class B/C – Annex IX
☐ Technical Documentation Assessment Class D – Annex IX
☐ Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
☐ Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
☐ Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

Certificates:

☒ EU QM Certificate No.: V10 092547 0022

☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):
V74 092547 0029

Other:	☐ Common Specifications:
Notified Body (NB) Name:	TÜV Süd Product Service GmbH
NB Address:	Ridlerstraße 65 80339 Munich Germany
NB Ident. No.:	0123

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.
and
fulfills the requirements of DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment. The standards applicable to the respective device under RoHS are listed below:

EN IEC 63000:2018

and
fulfills the requirements of Directive 2014/53/EU of the European Parliament and Council of 16 April 2014 (RED) relating to the making available on the market of radio equipment. The standards applicable to the respective device under RED are listed below:

IEC 61010-1:2010
IEC 61010-1:2010 AMD1:2016
IEC 61010-2-101:2018
EN 62479:2010
EN 301 489-1: V2.2.3
EN 301 489-17: V3.3.1
EN 300 328:V2.2.2
IEC 61010-1:2010/AMD1:2016/COR1:2019
and
fulfills the requirements of REGULATION (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries.

Mannheim, 10 March 2026

Roche Diabetes Care GmbH

i.V../on behalf of the company

Signed by:
Wolfgang Handel

Wolfgang Handel
Regulatory Affairs Expert

Mannheim, 11. März 2026

Roche Diabetes Care GmbH

ppa./on behalf of the company

Signed by:
Kai Kuellmer

Dr. Kai Kuellmer
Person Responsible for Regulatory Compliance
according to Art. 15 MDR/IVDR

Contact address:

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