



EU Declaration of Conformity

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

Manufacturer: Roche Diagnostics GmbH

Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number: DE-MF-000006260

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

Product Name	Cat. No. / REF	Basic UDI-DI
Micral-Test	11544039005	761333601635AV
Micral-Test	11544039171	761333601636AX
Micral-Test	11544039172	761333601637AZ

Intended Use:

30 test strips for the immunological, semi-quantitative in vitro determination of urinary albumin for evaluation by visual reading. Detection of microalbuminuria can aid diagnosis and treatment of incipient nephropathy in persons with diabetes and hypertension. In addition, microalbuminuria is a predictor in the general population for cardiovascular outcomes independent of other risk factors such as hyperlipidemia, hypertension or diabetes.

Micral-Test are test strips for single use only.

This test is intended for near-patient testing.

Not for self-testing.

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

Certificates:

- ☒ EU QM Certificate No.: V13 010283 0733
- ☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0672

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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Dr. Virginia Bastian

Aufsichtsratsvorsitzender: Dr. Thomas Schinecker



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.

Mannheim, 23. März 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
A blue ink signature of Nicole Zein, written in a cursive style.

Dr. Nicole Zein
Site Quality Head / Network Lead, Mannheim

Mannheim, 23 March 2026

Roche Diagnostics GmbH

i.V./on behalf of the company

Signed by:
A blue ink signature of Stefan Grigarczik, written in a cursive style.

Stefan Grigarczik
Subchapter Lead Global Regulatory Affairs

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