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.**	**Basic UDI-DI**
Combur^{10} Test UX	11544373191	761333601640AN
Combur^{10} Test UX	11544373173	761333601639B5
Combur^{10} Test UX	11544373049	761333601638B3
Combur^{10} Test UX	11544373170	761333601675B9
Combur^{10} Test UX	11544373243	761333601677BD
Combur^{10} Test UX	11544373171	761333601676BB
Combur^{10} Test UX	11544373005	761333601673B5
Combur^{10} Test UX	11544373053	761333601674B7
Combur^{10} Test UX	11544373343	761333601678BF
Combur^{10} Test UX	11544373370	761333602019A8

Intended Use:
The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions.
Not for self-testing.
The test is intended for near-patient 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 – Annex IX*

Roche Diagnostics 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 3962 - Geschäftsführung: Claus Haberda; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Certificates:	☒ *EU QM Certificate No.: V10 010283 0641* ☒ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0655*
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, 20 December 2022

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
Bernd Röttinger
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Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

i.V./*on behalf of the company*

DocuSigned by:
andreas finck
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Andreas Finck
Subchapter Lead Global Regulatory Affairs

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