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
Combur² Test LN	11896890191	761333601589BF
Combur² Test LN	11896890170	7613336020159Y
Combur³ Test	11896814191	761333601586B9
Combur³ Test	11896814056	761333601585B7
Combur³ Test	11896814170	761333602016A2
Combur³ Test E	11896857191	761333601588BD
Combur³ Test E	11896857170	761333602017A4
Combur⁴ Test N	11896822191	761333601587BB
Combur⁵ Test	11893467255	761333601584B5
Combur⁵ Test	11893467170	761333602018A6
Combur⁶ Test	11896962257	761333601591B2
Combur⁷ Test	11008552191	761333601594B8
Combur⁷ Test	11008552173	761333601593B6
Combur⁷ Test	11008552170	761333601679BH
Combur⁹ Test	04510046040	761333601275AM
Combur⁹ Test	04510054056	761333601276AP
Combur⁹ Test	04510038191	761333601274AK
Combur¹⁰ Test	04510089056	761333601278AT
Combur¹⁰ Test	04510062171	761333601277AR

Intended Use:

The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions.
The test is intended for near-patient testing.
Not for self-testing.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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 010283 0641* ☒ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0662*
Other:	☐ *Common Specifications:*
Notified Body (NB) Name: *NB Address:* *NB Ident. No.:*	*TÜV Süd Product Service GmbH* *Ridlerstraße 65* *80339 Munich* *Germany* *0123*

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

Mannheim, 17 January 2023

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Roettinger
00ABEBB0E89341C...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

Contact address:

Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim