

## **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*

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Combur <sup>2</sup> Test LN	11896890191	761333601589BF
Combur <sup>2</sup> Test LN	11896890170	7613336020159Y
Combur <sup>3</sup> Test	11896814191	761333601586B9
Combur <sup>3</sup> Test	11896814056	761333601585B7
Combur <sup>3</sup> Test	11896814170	761333602016A2
Combur <sup>3</sup> Test E	11896857191	761333601588BD
Combur <sup>3</sup> Test E	11896857170	761333602017A4
Combur <sup>4</sup> Test N	11896822191	761333601587BB
Combur <sup>5</sup> Test	11893467255	761333601584B5
Combur <sup>5</sup> Test	11893467170	761333602018A6
Combur <sup>6</sup> Test	11896962257	761333601591B2
Combur <sup>7</sup> Test	11008552191	761333601594B8
Combur <sup>7</sup> Test	11008552173	761333601593B6
Combur <sup>7</sup> Test	11008552170	761333601679BH
Combur <sup>9</sup> Test	04510046040	761333601275AM
Combur <sup>9</sup> Test	04510054056	761333601276AP
Combur <sup>9</sup> Test	04510038191	761333601274AK
Combur <sup>10</sup> Test	04510089056	761333601278AT
Combur <sup>10</sup> 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.

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: 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, 17 January 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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

ppa./on behalf of the company

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

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