



## **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   |
|--------------|-------------|----------------|
| cobas click  | 09355561190 | 761333602579BK |

### **Intended Use:**

The cobas click is an in vitro diagnostic instrument intended for quantitative evaluation of clinical chemistry assays and immunoassays using the cobas click test discs in human whole blood, plasma and serum. The cobas click instrument 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.:  
☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

**Other:** ☐ Common Specifications:

**Notified Body (NB) Name:** N/A

**NB Address:** N/A

**NB Ident. No.:** N/A

*to which this declaration relates fulfills 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.

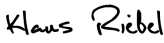
and

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.

Mannheim,

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:  
  
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Dr. Klaus Riebel

Network Lead Site Head Penzberg & Cape Town

Mannheim,

Roche Diagnostics GmbH

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