

## **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:** *cobas<sup>®</sup> pro ISE neo analyzer*

### **Intended use:**

The cobas pro ISE neo analyzer is intended for the quantitative determination of Chloride (Cl<sup>-</sup>), Sodium (Na<sup>+</sup>) and Potassium (K<sup>+</sup>) in serum, plasma or urine using ion selective electrodes.

### **List of components:**

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
cobas ISE neo 900 analytical unit	09687432001	761333602774BK
cobas ISE neo 1800 analytical unit	09687416001	761333602775BM

### **Intended Use:**

A configurable device that is used for ion selective electrode analysis in the cobas pro integrated solutions, for in-vitro determinations.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
cobas pro SSU	09205632001	761333602893BU

### **Intended Use:**

A configurable device that allows loading and unloading of racks with sample containers and delivers them to the transportation line.

**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 fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

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, 3 June 2024

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*

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

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