

## **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
PHOS2	03183793122	7613336002099Z

### ***Intended Use:***

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
PHOS2	05171377190	7613336000389W
PHOS2	05171377214	7613336000419K
PHOS2	08058610190	7613336000139E

### ***Intended Use:***

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
PHOS2	05401780190	761333600095AA

### ***Intended Use:***

In vitro test for the quantitative determination of the inorganic phosphate concentration in human serum, plasma and urine on the cobas c 111 system.

**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.: V12 010283 0639*  
 *EU Technical Documentation Assessment Certificate No.*  
*(Class D, Near-Patient Testing, Self-Testing and Companion*  
*Diagnostics):*

*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, 13 September 2023

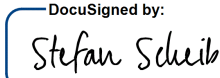
Roche Diagnostics GmbH

*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

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