

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:

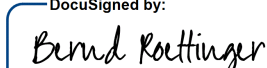
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
Germany
NB Ident. No.: 0123

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

Mannheim, 13 September 2023

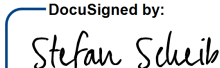
Roche Diagnostics GmbH

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

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