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, under the sole responsibility, declares that the product/the product line

Product Name	**Cat. No.**	**Basic UDI-DI**
cobas p 612 pre-analytical system	08166145001	761333602134A9
cobas p 612 pre-analytical system	07962673001	761333602134A9
cobas p 612 pre-analytical system	07962665001	761333602134A9
cobas p 612 pre-analytical system	07962703001	761333602134A9
cobas p 612 pre-analytical system	09639977001	761333602134A9
cobas p 612 pre-analytical system	09639985001	761333602134A9
cobas p 612 pre-analytical system	09639942001	761333602134A9
cobas p 612 pre-analytical system	09639969001	761333602134A9

Intended Use:

cobas p 612 pre-analytical system is a computercontrolled fully automatic system for sorting of open and closed barcoded, centrifuged, and non-centrifuged sample tubes. It is used with analyzers that perform tests in the area of clinical chemistry, immuno chemistry, coagulation, hematology, urinanalysis, nucleic acid, and allergy testing.

It includes modules for registration and decapping of sample tubes, liquid level detection, and sample quality assessment (optional), recapping of sample tubes (optional), barcode printing, as well as aliquoting of primary and secondary tubes.

In case of standalone use of the pre-analytical system, the transfer of tubes processed on the pre-analytical system to any other workstation within the laboratory is a subject of validation performed by laboratory itself.

Risk Class: ☒ *A* ☐ *B* ☐ *C* ☐ *D*

Conformity Route:
☒ *Self-Declaration of Conformity (Class A)*
☐ *Technical Documentation Assessment Class B/C – 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*

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Certificates:	☐ *EU QM Certificate No.:* ☐ *EU Technical Documentation Assessment Certificate No. (Near-Patient Testing, Self-Testing and Companion Diagnostics):*
Other:	☐ *Common Specifications:*
Notified Body (NB) Name: *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
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.*

Mannheim, 16 February 2023

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
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Dr. Christina Schmid
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