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*: cobas® pure integrated solutions*

Intended Use:
cobas® pure integrated solutions is an automated analyzer, intended for running qualitative and quantitative clinical chemistry and immunochemistry assays as well as ion selective measurements.

List of components:

Product Name	Cat. No.	Basic UDI-DI
sample supply unit	09031537001	761333602903B6

Intended Use:
A configurable device that allows loading and unloading of racks with sample containers and delivers them to each analytical unit.

Product Name	Cat. No.	Basic UDI-DI
cobas e 402 analytical unit	09031553001	761333602905BA

Intended Use:
A configurable device that is used for immunoassay analysis in the cobas pure integrated solutions, for in-vitro determinations.

Product Name	Cat. No.	Basic UDI-DI
cobas c 303 analytical unit	09031529001	761333602904B8

Intended Use:
A configurable device that is used for photometric and ion selective electrode analysis in cobas pure integrated solutions, for in-vitro determinations.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Product Name	Cat. No.	Basic UDI-DI
cobas pure liquid waste container	09033394001	761333602964BS

Intended Use:
An optional accessory that is used to drain low concentrated liquid waste for e402.

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*

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: *N/A*
NB Address:

NB Ident. No.: *N/A*

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

Starting with Serial No.:

Product/ component name	Serial No.
sample supply unit	From 2301-01 onward
cobas e 402 analytical unit	From 2301-01 onward
cobas c 303 analytical unit	From 2301-01 (Naka) and T301-01 (Omuta) onward
cobas pure liquid waste container	From 230001-01 onward

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, 9 January 2024

Roche Diagnostics GmbH

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

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

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

Contact address:

Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
68305 Mannheim
Germany