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® pro integrated solutions*

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

List of components:

Product Name	Cat. No.	Basic UDI-DI
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.

Product Name	Cat. No.	Basic UDI-DI
cobas pro SB	09205675001	761333602894BW
cobas pro SBL c 503	09205691001	761333602895BY
cobas pro SBL e 801	09211888001	761333602896C2

Intended Use:
A configurable device that buffers and transports racks with sample containers into the analytical units of cobas pro integrated solutions, for in-vitro determinations.

Product Name	Cat. No.	Basic UDI-DI
cobas pro transport line	09205683001	761333602897C4

Intended Use:
A configurable device that transports racks with sample containers among the sample supply unit and analytical units of cobas pro integrated solutions.

Product Name	Cat. No.	Basic UDI-DI
cobas pro Transport Belt (2 AU, 2 ISE)	09205713001	761333602907BE
cobas pro Transport Belt (3 AU, 2 ISE)	09205721001	
cobas pro Transport Belt (4 AU, 2 ISE)	09205730001	

Intended Use:
A configurable device used together with the cobas pro transport line that transports racks with sample containers among the sample supply unit and analytical units of cobas pro integrated solutions.

Product Name	Cat. No.	Basic UDI-DI
cobas pro A-Gate Upgrade Kit	09813799001	761333602902B4

Intended Use:
An optional accessory that is used for the connection of cobas pro sample supply unit to a unidirectional pre-analytical system.

Product Name	Cat. No.	Basic UDI-DI
cobas pro B-Gate Upgrade Kit	09205756001	761333602898C6
cobas pro B-Gate update kit	08763640001	761333602899C8

Intended Use:
An optional accessory that is used for the connection of cobas pro sample supply unit to a bidirectional pre-analytical system.

Product Name	Cat. No.	Basic UDI-DI
cobas pro liquid waste container	08763704001	761333602900AY

Intended Use:
An optional accessory that is used to collect concentrated liquid waste material of the analytical units of cobas pro integrated solutions.

Product Name	Cat. No.	Basic UDI-DI
cobas pro ISE analytical unit	08464537001	761333602892BS

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

Product Name	Cat. No.	Basic UDI-DI
cobas c 503 analytical unit	08463662001	761333602891BQ

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

Product Name	Cat. No.	Basic UDI-DI
cobas e 801 analytical unit	08454345001	761333602880BK

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

Product Name	Cat. No.	Basic UDI-DI
3000m Liq.Fl.Path Mod.kit e801	09075704001	761333602901B2

Intended Use:
An optional accessory that is used for modifying the cobas pro e 801 analyzer so that it is possible to be operated in altitudes between 2000 m and 3000 m above sea level.

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.
cobas pro SSU	From 2301-01 / C301-01 onward
cobas pro SB	From 2301-01 / C301-01 onward
cobas pro SBL c 503	From 2301-01 / C301-01 onward
cobas pro SBL e 801	From 2301-01 / C301-01 onward
cobas pro transport line	From 2301-01 / C301-01 onward
cobas pro Transport Belt (2 AU, 2 ISE)	From Lot 2023-01-01 onward
cobas pro Transport Belt (3 AU, 2 ISE)	From Lot 2023-01-01 onward
cobas pro Transport Belt (4 AU, 2 ISE)	From Lot 2023-01-01 onward
cobas pro A-Gate Upgrade Kit	From 233573-01 onward
cobas pro B-Gate Upgrade Kit	From 233579-01 onward
cobas pro B-Gate update kit	Shipment from 15th September 2023 onward
cobas pro liquid waste container	From 232151-01 onward

cobas c 503 analytical unit	From 2301-01 onward
cobas e 801 analytical unit	From 4301-01 onward
cobas pro ISE analytical unit	From 2301-01 onward
3000m Liq.Fl.Path Mod.kit e801	From 231251-01 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, 28 September 2023

Roche Diagnostics GmbH

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

DocuSigned by:
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00ABEBB0E89341C...

Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

ppa./*on behalf of the company*

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