



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® 8000 modular analyzer series*

Intended Use:

The cobas® 8000 modular analyzer series 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 8000 Core Unit	05641446001	761333602877BW

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 8000 c 701 Module	05641489001	761333602878BY

Intended Use:

A configurable device that is used for photometric analysis in the cobas 8000 modular analyzer series, for in-vitro determinations.

Product Name	Cat. No.	Basic UDI-DI
cobas 8000 c 702 Module	06473245001	761333602879C2

Intended Use:

A configurable device that is used for photometric analysis in the cobas 8000 modular analyzer series, for in-vitro determinations. It includes a reagent auto-loading unit (reagent manager) to exchange reagent cassettes on the c702 reagent disk.



Product Name	Cat. No.	Basic UDI-DI
cobas e 801 MSB/MSBL	08459606001	761333602881BM

Intended Use:

A configurable device that buffers and transports racks with sample containers into the cobas e 801 analytical unit of cobas 8000 modular analyzer series, for in-vitro determinations.

Product Name	Cat. No.	Basic UDI-DI
cobas 8000 ISE 900 Module	05641497001	761333602882BP

Intended Use:

A configurable device that is used for ion selective electrode analysis in the cobas 8000 modular analyzer series, for in-vitro determinations, with a throughput of 900 tests per hour.

Product Name	Cat. No.	Basic UDI-DI
cobas 8000 ISE 1800 Module	05964075001	761333602883BR

Intended Use:

A configurable device that is used for ion selective electrode analysis in the cobas 8000 modular analyzer series, for in-vitro determinations, with a throughput of 1800 tests per hour.

Product Name	Cat. No.	Basic UDI-DI
cobas 8000 Transport Line	05641519001	761333602884BT

Intended Use:

A configurable device that transports racks with sample containers among the Core Unit and analytical units of cobas 8000 modular analyzer series.

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 8000 Core Unit	From 2401-01 onward
cobas 8000 c 701 Module	From 2401-01 onward
cobas 8000 c 702 Module	From 2401-01 onward
cobas e 801 MSB/MSBL	From 2401-01 onward
cobas 8000 ISE 900 Module	From 2401-01 onward
cobas 8000 ISE 1800 Module	From 2401-01 onward
cobas 8000 Transport Line	From 2401-01 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, 23 January 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

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