

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
Sample Cup	10394246001	761333601962BF

Intended Use:

The Sample Cup is an IVD accessory intended to be used with the following systems:

- COBAS INTEGRA® 400 plus analyzer
- MODULAR PRE-ANALYTICS EVO
- cobas c 111 analyzer
- cobas c 303 analytical unit
- cobas c 311 analyzer
- cobas e 402 analytical unit
- cobas e 411 analyzer
- cobas c 501 module
- cobas c 502 module
- cobas c 503 analytical unit
- cobas e 601 module
- cobas e 602 module
- cobas c 701 module
- cobas c 702 module
- cobas e 801 module
- cobas e 801 analytical unit
- cobas 8000 ISE 900 module
- cobas 8000 ISE 1800 module
- cobas pro ISE analytical unit

For professional use only.

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.:
 EU Technical Documentation Assessment Certificate No.
(Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: Common Specifications:

Notified Body (NB) Name: N/A
NB Address:

NB Ident. No.: N/A

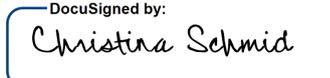
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

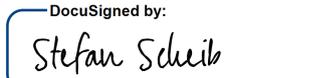
Mannheim, 19 June 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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