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 c 703 analytical unit
- cobas e 801 module
- cobas e 801 analytical unit
- cobas 8000 ISE 900 module
- cobas 8000 ISE 1800 module
- cobas pro ISE analytical unit
- ISE neo 900 analytical unit
- ISE neo 1800 analytical unit

For professional use only.

Digitally signed by Lazari Cristina
Date: 2024.11.18 15:55:38 EET
Reason: MoldSign Signature
Location: Moldova

Risk Class: ☒ A ☐ B ☐ C ☐ D

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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:	*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.

Mannheim, 3 July 2024

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
485913ABEB04408...

Dr. Peer Lorenz
Site Quality Head / Network Lead, Mannheim

ppa./*on behalf of the company*

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

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