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
ECO-D	05422485190	761333601366AR

Intended Use:
EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c 311 systems.

Product Name	Cat. No.	Basic UDI-DI
ECO-D	05907543190	761333601389B5
ECO-D	05907543214	761333601390AN
ECO-D	06544410190	761333601435AK
ECO-D	08063354190	761333601533AL
ECO-D	08063354214	761333602591B9

Intended Use:
EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c systems.

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

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; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Digitally signed by Lazari Cristina
Date: 2024.11.18 15:54:16 EET
Reason: MoldSign Signature
Location: Moldova

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, 6 November 2024

Roche Diagnostics GmbH

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

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