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Role:	Approver
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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

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*

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

Other: ☐ *Common Specifications:*

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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Vorsitzender: Dr. Thomas Schinecker

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, 11 September 2023

Roche Diagnostics GmbH

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

DocuSigned by:
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