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
NaCl Diluent 9%	04774230190	761333601318AE

Intended Use:
NaCl Diluent 9% is used as a sample diluent in conjunction with assay reagents on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
NACL	04489357190	761333601272AF
NACL	05172152190	761333601357AQ
NACL	05172152214	761333601358AS
NACL	08063494190	761333601536AS
NACL	08063494214	761333602592BB

Intended Use:
Diluent NaCl 9 % is used as a sample diluent in conjunction with assay reagents on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
NaCl Diluent 9%	20756350322	761333601659BB

Intended Use:
NaCl Diluent 9% is used as a sample diluent in conjunction with assay reagents on COBAS INTEGRA 400 plus analyzers.

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

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

	☐ 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, 29 August 2024

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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

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