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
AST	05850819190	761333600364AE

Intended Use:

In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum and plasma on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
ASTLP	04467493190	761333600266AD
ASTPM	05531446190	761333600337AB
ASTP	08056838190	761333600509AG

Intended Use:
In vitro test for the quantitative determination of aspartate aminotransferase (AST) with pyridoxal phosphate activation in human serum and plasma on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
ASTL	04657543190	761333600296AN

Intended Use:
In vitro test for the quantitative determination of aspartate aminotransferase, with or without pyridoxal phosphate activation, in human serum and plasma on cobas c 111 systems.

Product Name	Cat. No.	Basic UDI-DI
ASTL	20764949322	7613336001629Y

Intended Use:
In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum and plasma on cobas c and COBAS INTEGRA systems.

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; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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.: *V12 010283 0639*
	☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):
Other:	☐ Common Specifications:
Notified Body (NB) Name:	TÜV Süd Product Service GmbH
NB Address:	Ridlerstraße 65 80339 Munich Germany
NB Ident. No.:	0123

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

Mannheim, 12 August 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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