

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.

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

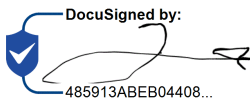
NB Ident. No.: 0123

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

DocuSigned by:

FC5EDEC1054B44C...

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

Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs



Sandhofer Strasse 116
D-68305 Mannheim