

EC 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
Urisys 1100	03617548001	761333601269AS
Urisys 1100	03617548016	7613336021009Q
Urisys 1100	03617548170	7613336021019S
Urisys 1100	03617548345	7613336021029U
Urisys 1100	03617548343	7613336021039W

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:*

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.

and

- fulfills the requirements of DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Mannheim, 20 January 2022

Roche Diagnostics GmbH


ppa./on behalf of the company

DocuSigned by:

A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

i.V./on behalf of the company

DocuSigned by:

ED7C986D7264465...

Dr. Thomas Mall
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim