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**
cobas h 232	04901126190	761333601340A7
cobas h 232	04901126041	761333602325AJ
cobas h 232	04901126026	761333602326AL
cobas h 232	04901126016	761333602327AN
cobas h 232	04901126005	761333602328AQ
cobas h 232	04901126045	761333602329AS
cobas h 232	04901126037	761333602330AB
cobas h 232	04901126057	761333602331AD
cobas h 232	04901126060	761333602332AF
cobas h 232	04901126134	761333602333AH
cobas h 232	04901126039	761333602334AK
cobas h 232	04901126051	761333602335AM
cobas h 232	04901126053	761333602336AP
cobas h 232	04901142190	761333601341A9
cobas h 232	04901142041	761333602337AR
cobas h 232	04901142026	761333602338AT
cobas h 232	04901142016	761333602339AV
cobas h 232	04901142005	761333602340AE
cobas h 232	04901142037	761333602341AG
cobas h 232	04901142057	761333602342AJ
cobas h 232	04901142013	761333602343AL
cobas h 232	04901142245	761333602344AN
cobas h 232	04901142060	761333602345AQ
cobas h 232	04901142134	761333602346AS
cobas h 232	04901142039	761333602347AU
cobas h 232	04901142051	761333602348AW
cobas h 232	04901142220	761333602349AY
cobas h 232	04901142053	761333602350AH

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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: *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

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.*
- *fulfills the requirements of Directive 2014/53/EU of the European Parliament and Council of 16 April 2014 (RED) relating to the making available on the market of radio equipment.*

Mannheim, 11 March 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
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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
Specialty SubChapter Lead,
Global Regulatory Affairs
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