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
cobas click	09355561190	761333602579BK

Intended Use:
The cobas click is an in vitro diagnostic instrument intended for quantitative evaluation of clinical chemistry assays and immunoassays using the cobas click test discs in human whole blood, plasma and serum. The cobas click instrument is intended for near-patient testing. Not for self-testing.

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:

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

Notified Body (NB) Name:	*N/A*
NB Address:	*N/A*
NB Ident. No.:	*N/A*

to which this declaration relates fulfills 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.

and

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, 12 May 2025

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
Klaus Riebel
5E57330EEFE04C4...

Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

Mannheim, 09. Mai 2025

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

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

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