

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
Elecsys Cortisol	11875116122	761333600740AL

Intended Use:

Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma, urine, and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Cortisol CalSet	11875124122	761333600741AN

Intended Use:

Cortisol CalSet is used for calibrating the quantitative Elecsys Cortisol assay on the Elecsys and cobas e immunoassay analyzers.

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:
NB Address:

TÜV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
0123

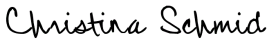
NB Ident. No.:

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

Mannheim, 26 April 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

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Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

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