

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 III Urine	09290915190	761333600830AN
Elecsys Cortisol III	07682808190	761333600831AQ

Intended Use:

Immunoassay for the in vitro quantitative determination of cortisol in human urine. 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 cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CalSet Cortisol III Urine	09290940190	761333600834AW

Intended Use:

CalSet Cortisol III Urine is used for calibrating the quantitative Elecsys Cortisol III (urine application) and Elecsys Cortisol III Urine immunoassays on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
PreciControl Cortisol Urine	06687776190	761333600835AY

Intended Use:

PreciControl Cortisol Urine is used for quality control of the Elecsys Cortisol III (urine application) and Elecsys Cortisol III Urine immunoassays on 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:

NB Ident. No.:

TÜV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
0123

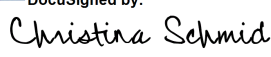
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 27 March 2023

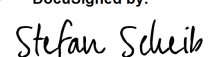
Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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

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