

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 Progesterone III	07092539190	761333600408A9
Elecsys Progesterone III	07027699190	761333600395AR
Elecsys Progesterone III	07027699214	761333602060A5

Intended Use:

Immunoassay for the in vitro quantitative determination of progesterone in human serum and plasma.
 The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Progesterone III CalSet	07092547190	761333600409AB

Intended Use:

Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone III assay 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: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
Germany
NB Ident. No.: 0123

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

Mannheim, 12 January 2023

Roche Diagnostics GmbH

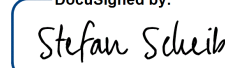
i.V./on behalf of the company

DocuSigned by:

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

ppa./on behalf of the company

DocuSigned by:

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

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