

## **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*

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys ACTH	08946710190	761333601144A5
Elecsys ACTH	08946728190	761333601145A7
Elecsys ACTH	08946728214	761333602768BQ

### ***Intended Use:***

Immunoassay for the in vitro quantitative determination of adrenocorticotrophic hormone (ACTH) in human EDTA plasma.

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
ACTH CalSet	08959820190	761333601146A9

### ***Intended Use:***

ACTH CalSet is used for calibrating the quantitative Elecsys ACTH 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, 30 January 2024

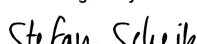
Roche Diagnostics GmbH

i.V./on behalf of the company

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

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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys AFP	09015060190	761333602241AB
Elecsys AFP	09015086190	761333602242AD
Elecsys AFP	09015124190	761333602243AF
Elecsys AFP	09731385190	761333602956BT

### ***Intended Use:***

Immunoassay for the in vitro quantitative determination of  $\alpha$ 1-fetoprotein in human serum and plasma.

This assay is intended for the use as:

- An aid in the diagnosis of hepatocellular carcinoma (HCC).
- An aid in the management of patients with non-seminomatous germ cell tumors.
- One component in combination with other parameters to evaluate the risk of trisomy 21 (Down syndrome).  
 Further testing is required for diagnosis of chromosomal aberrations.

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
AFP CalSet II	09227261190	761333602244AH

### ***Intended Use:***

AFP CalSet II is used for calibrating the quantitative Elecsys AFP 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  
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*NB Ident. No.:* 0123

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

Mannheim, 31 January 2024

Roche Diagnostics GmbH

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

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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys Anti-CCP	05031656190	761333600952B5

### ***Intended Use:***

Immunoassay for the in vitro semi-quantitative determination of human IgG autoantibodies to cyclic citrullinated peptides in human serum. The results of the assay are intended to be used as an aid in the diagnosis of rheumatoid arthritis in combination with other clinical and laboratory findings.

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
PreciControl Anti-CCP	05031664190	761333600953B7

### ***Intended Use:***

PreciControl Anti-CCP is used for quality control of the Elecsys Anti-CCP immunoassay on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys Anti-CCP	07251670190	761333600999BX

### ***Intended Use:***

Immunoassay for the in vitro semi-quantitative determination of human IgG autoantibodies to cyclic citrullinated peptides in human serum. The results of the assay are intended to be used as an aid in the diagnosis of rheumatoid arthritis in combination with other clinical and laboratory findings.

The electrochemiluminescence immunoassay "ECLIA" is intended for use 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:

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Mannheim, 26 April 2023


Roche Diagnostics GmbH

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