

## **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 ACTH | 08946710190 | 761333601144A5 |
| Elecsys ACTH | 08946728190 | 761333601145A7 |

### ***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.

| Product Name | Cat. No.    | Basic UDI-DI   |
|--------------|-------------|----------------|
| 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:  
NB Address:

TÜV Süd Product Service GmbH  
Ridlerstraße 65  
80339 Munich  
Germany  
0123

NB Ident. No.:

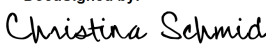
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 12 April 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:  
  
E3965E80F3E840E...

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

DocuSigned by:  
  
FC5EDEC1054B44C...

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

Contact address:

Roche Diagnostics GmbH  
Abt./Dept. Global Regulatory Affairs  
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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      |

### ***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:

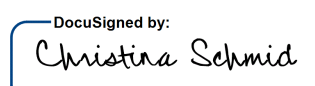
Notified Body (NB) Name: TÜV Süd Product Service GmbH  
NB Address: Ridlerstraße 65  
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Germany  
NB Ident. No.: 0123

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

Mannheim, 12 April 2023

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| <b>Product Name</b> | <b>Cat. No.</b> | <b>Basic UDI-DI</b> |
|---------------------|-----------------|---------------------|
| Elecsys Anti-Tg     | 09004998190     | 7613336011419X      |
| Elecsys Anti-Tg     | 09005021190     | 7613336011429Z      |

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

Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. 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> |
|---------------------|-----------------|---------------------|
| Anti-Tg CalSet      | 09005030190     | 761333601143A3      |

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

Anti-Tg CalSet is used for calibrating the quantitative Elecsys Anti-Tg 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:

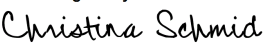
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Global Head of Regulatory Affairs, Core Lab

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D-68305 Mannheim



## EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998  
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Professional Diagnostics  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)  
*Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)*

Produktname/Product name: **AssayCup**

Art.-Nr./Id. No.: 11706802001

Beschreibung/Description: The AssayCup is intended to be used as an IVD accessory on the following systems:  
**cobas e 411 analyzer**  
**Elecsys® 2010 analyzer**

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.  
*to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.*

Mannheim, 30. Jul. 2013  
Roche Diagnostics GmbH  
ppa./on behalf of the company

Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics

Rotkreuz, 30. Jul. 2013  
Roche Diagnostics International Ltd  
ppa./on behalf of the company

Ralf Zielenski  
Head of Quality GPS and RDI  
Roche Diagnostics International Ltd

Kontaktadresse/Contact address: Roche Professional Diagnostics  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Strasse 116  
68305 Mannheim  
Germany  
Fax: +49 621/759 1448





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*Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)*

Produktname/Product name: **AssayTip**  
Art.-Nr./Id. No.: 11706799001  
Beschreibung/Description: The AssayTip is intended to be used as an IVD accessory on the following systems:  
**cobas e 411 analyzer**  
**Elecsys® 2010 analyzer**

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.  
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