

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 CA 125 II	11776223190	7613336001369X
Elecsys CA 125 II	11776223214	761333602082AF

Intended Use:

Immunoassay for the in vitro quantitative determination of OC 125 reactive determinants in human serum and plasma. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer (excluding those with cancer of low malignant potential). This assay is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for second-look procedures. This assay is further indicated for serial measurement of CA 125 to aid in the management of cancer patients. This assay is also intended to be used in conjunction with the Elecsys HE4 assay as part of ROMA (Risk Of Ovarian Malignancy Algorithm) for the risk assessment of ovarian cancer in premenopausal and postmenopausal women presenting with pelvic mass.

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 125 II	07026986190	761333600245A5
Elecsys CA 125 II	07026986214	761333602048AF

Intended Use:

Immunoassay for the in vitro quantitative determination of OC 125 reactive determinants in human serum and plasma. These determinants are associated with a high molecular weight glycoprotein in serum and plasma of women with primary epithelial invasive ovarian cancer (excluding those with cancer of low malignant potential). This assay is indicated for use as an aid in the detection of residual or recurrent ovarian carcinoma in patients who have undergone first-line therapy and would be considered for second-look procedures. This assay is further indicated for serial measurement of CA 125 to aid in the management of cancer patients. This assay is also intended to be used in conjunction with the Elecsys HE4 assay as part of ROMA (Risk Of Ovarian Malignancy Algorithm) for the risk assessment of ovarian cancer in pre- and postmenopausal women presenting with pelvic mass. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CA 125 II CalSet II	07030207190	761333600406A5

Intended Use:

CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II 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 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

 E3965E80F3E840E...

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

ppa./on behalf of the company

DocuSigned by:

 FC5EDEC1054B44C...

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

Contact address: Roche Diagnostics GmbH
 Abt./Dept. Global Regulatory Affairs
 Sandhofer Strasse 116
 D-68305 Mannheim

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Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 19-9	11776193122	761333600730AH
Elecsys CA 19-9	11776193214	761333602081AD

Intended Use:

Immunoassay for the in vitro quantitative determination of CA 19-9 in human serum and plasma.

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 19-9	07027028190	761333600799BM
Elecsys CA 19-9	07027028214	761333602050A2

Intended Use:

Immunoassay for the in vitro quantitative determination of CA 19-9 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
CA 19-9 CalSet	11776215122	761333600732AM

Intended Use:

CA 19-9 CalSet is used for calibrating the quantitative Elecsys CA 19-9 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:

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- ☐ *Common Specifications:*

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NB Ident. No.:

*TÜV Süd Product Service GmbH
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Mannheim, 15 March 2023

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Head of Pre-Market Quality Core Lab

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DocuSigned by:
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Product Name	Cat. No.	Basic UDI-DI
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.

Product Name	Cat. No.	Basic UDI-DI
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.

Product Name	Cat. No.	Basic UDI-DI
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:

Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
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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, 26 April 2023

Roche Diagnostics GmbH


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

ppa./on behalf of the company

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Product Name	Cat. No.	Basic UDI-DI
Elecsys CEA	11731629322	7613336001349T

Intended Use:

Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma. This assay is further indicated for serial measurement of CEA to aid in the management of cancer patients. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys CEA	07027079190	761333600248AB
Elecsys CEA	07027079214	761333602051A4

Intended Use:

Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma. This assay is further indicated for serial measurement of CEA to aid in the management of cancer patients. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys CEA	04491777190	761333600279AN

Intended Use:

Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma. This assay is further indicated for serial measurement of CEA to aid in the management of cancer patients. The electrochemiluminescence immunoassay "ECLIA" is intended for use on MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CEA CalSet	11731645322	7613336001359V

Intended Use:

CEA CalSet is used for calibrating the quantitative Elecsys CEA 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:

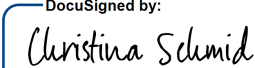
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
Germany
NB Ident. No.: 0123

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

Mannheim, 14 November 2022

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

59311CC1CDA8480...

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

ppa./on behalf of the company

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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Product Name	Cat. No.	Basic UDI-DI
CleanCell	11662970122	761333601644AW

Intended Use:

System solution for cleaning the detection unit of the cobas e 411 immunoassay analyzer.
 CleanCell is used in conjunction with Elecsys assay reagents.
 CleanCell can be used with all reagent lots.

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.:
☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

Notified Body (NB) Name: N/A
NB Address:

NB Ident. No.: N/A

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

Mannheim, 16 June 2023

Roche Diagnostics GmbH

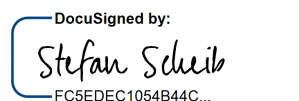
i.V./on behalf of the company

DocuSigned by:

E3965E80E3E840E

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

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B4C...

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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:

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Ridlerstraße 65
80339 Munich
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0123

NB Ident. No.:

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Mannheim, 26 April 2023

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Product Name	Cat. No.	Basic UDI-DI
Elecsys C-Peptide	03184897190	761333600931AV
Elecsys C-Peptide	03184897214	761333602044A7

Intended Use:

Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys C-Peptide	07027168190	761333600993BK
Elecsys C-Peptide	07027168214	761333602053A8

Intended Use:

Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
C-Peptide CalSet	03184919190	761333600932AX

Intended Use:

C-Peptide CalSet is used for calibrating the quantitative Elecsys C-Peptide 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*
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Other:

☐ *Common Specifications:*

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Mannheim, 30 March 2023

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Product Name	Cat. No.	Basic UDI-DI
Elecsys DHEA-S	03000087122	761333600572AP

Intended Use:

Immunoassay for the in vitro quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) in human serum and plasma.

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys DHEA-S	07027192190	761333600801AF

Intended Use:

Immunoassay for the in vitro quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) 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
DHEA-S CalSet	03000095122	761333600573AR

Intended Use:

Intended use DHEA-S CalSet is used for calibrating the quantitative Elecsys DHEA-S 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
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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 Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

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: **Diluent Universal**

Art.-Nr./Id. No.: **11732277**

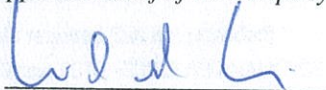
Beschreibung/Description: Diluent Universal dient als Verdünnungsmedium für Proben in Verbindung mit Elecsys Test-Reagenzien.
Diluent Universal is used as a sample diluent in conjunction with Elecsys assay reagents.

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, 19.07.2013

Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

i. V./on behalf of the company



Dr. C. Fleischer
Head of Quality Control Penzberg
Roche Diagnostics Global Operations

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

11732277_Diluent Universal - Ia

Roche Diagnostics GmbH Diagnostics Division

Roche Diagnostics GmbH; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher: Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan