EG-Konformitätserklärung/*EC Declaration of Conformity*

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)
as per Annex IV of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)

Hersteller/*Manufacturer*:	Roche Diagnostics GmbH
Adresse/*Address:*	Sandhofer Strasse 116 D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/*Product name*:	**Elecsys Anti-HBs II**
Art.-Nr./*Cat. No.*:	**08498598190**
Beschreibung/*Description*:	Immunologischer In-vitro-Test zur quantitativen Bestimmung von Humanantikörpern gegen das Hepatitis-B-Oberflächenantigen (HBsAg) in Humanserum und -plasma. Der **E**lektro**C**hemi**L**umineszenz **I**mmuno**A**ssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen. *Immunoassay for the in vitro quantitative determination of human antibodies to the hepatitis B surface antigen (HBsAg) in human serum and plasma.* *The **e**lectrochemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.*

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

Mannheim, 3 September 2019

Roche Diagnostics GmbH

ppa./*on behalf of the company*
ppa. Dr. Lydia Langen

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*
i.V. Dr. Joachim Hoch

Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
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Digitally signed by Lazari Cristina
Date: 2023.11.23 16:44:05 EET
Reason: MoldSign Signature
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Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Ursula Redeker, Sprecherin; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Severin Schwan

Amendment to IVDD EC Declaration of Conformity

pursuant to Article 110 (3) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany

This amendment is only valid in combination with the following EC Declaration of Conformity (IVDD):

Product Name: Elecsys Anti-HCV II

Cat. No.:
08836981190
08837031190
08837058190

Signed on: 09-Feb-2022

This Amendment confirms the validity of the aforementioned EC Declaration of Conformity (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.

Description of change:
Addition of a new catalogue number 08837058192 for a new package size ("multi pack/maxi pack") of the product Elecsys Anti-HCV II.

Intended use:
Der Elecsys Anti-HCV II Test ist ein diagnostischer In-vitro-Test für den qualitativen Nachweis von Antikörpern gegen Hepatitis-C-Virus (HCV) in Humanserum und -plasma.
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.
The Elecsys Anti-HCV II assay is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Mannheim, 2 August 2023

Roche Diagnostics GmbH

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

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

ppa./*on behalf of the company*

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Global Head of Regulatory Affairs, Core Lab

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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 Active B12	07713207190	761333600488AZ

Intended Use:
Immunoassay for the in vitro quantitative determination of active vitamin B12 (holotranscobalamin) in human serum. The assay is used as an aid in the diagnosis and treatment of vitamin B12 deficiency.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
Elecsys Active B12	07713258190	761333600490AL

Intended Use:
Immunoassay for the in vitro quantitative determination of active vitamin B12 (holotranscobalamin) in human serum. The assay is used as an aid in the diagnosis and treatment of vitamin B12 deficiency.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas e 801 immunoassay analyzer.

Product Name	**Cat. No.**	**Basic UDI-DI**
CalSet Active B12	07726350190	761333600491AN

Intended Use:
CalSet Active B12 is used for calibrating the quantitative Elecsys Active B12 assay on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
PreciControl Active B12	07713223190	761333600489B3

Intended Use:
PreciControl Active B12 is used for quality control of the Elecsys Active B12 immunoassay on cobas e immunoassay analyzers.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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, 10 March 2023

Roche Diagnostics GmbH

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

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Dr. Christina Schmid
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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 Calcitonin	09005668190	761333601135A4
Elecsys Calcitonin	09005676190	761333601136A6

Intended Use:
Immunoassay for the in vitro quantitative determination of human calcitonin (thyrocalcitonin) in serum and plasma. The calcitonin determination is intended to be used as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism in conjunction with other clinical and laboratory findings.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
Calcitonin CalSet	09005684190	761333601137A8

Intended Use:
Calcitonin CalSet is used for calibrating the quantitative Elecsys Calcitonin 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*

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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, 31 March 2023

Roche Diagnostics GmbH

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

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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 Folate III	08324131190	761333601151A2

Intended Use:
Binding assay for the in vitro quantitative determination of folate in human serum and plasma. Folate measurements, performed with the Elecsys Folate III assay, are used as an aid in diagnosis and monitoring of folate imbalance.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
Elecsys Folate III	08324174190	761333601153A6

Intended Use:
Binding assay for the in vitro quantitative determination of folate in human serum, plasma and erythrocytes (red blood cells, RBC). Folate measurements, performed with the Elecsys Folate III assay, are used as an aid in diagnosis and monitoring of folate imbalance.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
Folate III CalSet	08324182190	761333601152A4

Intended Use:
Folate III CalSet is used for calibrating the quantitative Elecsys Folate III assay on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
CalSet Folate	08324247190	761333601154A8

Intended Use:
CalSet Folate is used for calibrating the quantitative Elecsys Folate III assay on cobas e immunoassay analyzers.

Risk Class: ☐ *A* ☒ *B* ☐ *C* ☐ *D*

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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, 19 July 2023

Roche Diagnostics GmbH

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

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Amendment to IVDD EC Declaration of Conformity

pursuant to Article 110 (3) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany

This amendment is only valid in combination with the following EC Declaration of Conformity (IVDD):

Product Name: Elecsys Anti-HBc II

Cat. No.: 09014926190

Signed on: 31-May-2021

This Amendment confirms the validity of the aforementioned EC Declaration of Conformity (IVDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.

Description of change:
Addition of a new catalogue number 09014926192 for a new package size (“multi pack/maxi pack”) of the product Elecsys Anti-HBc II.

Intended Use:
Immunologischer In-vitro-Test zur qualitativen Bestimmung der IgG- und IgM-Antikörper gegen das Hepatitis B-Core-Antigen in Humanserum und-plasma.
Der ElektroChemiLumineszenz ImmunoAssay “ECLIA“ ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.

Immunoassay for the in vitro qualitative determination of IgG and IgM antibodies to the hepatitis B core antigen in human serum and plasma.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Mannheim, 21 August 2023

Roche Diagnostics GmbH

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

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Amendment to IVDD EC Declaration of Conformity

pursuant to Article 110 (3) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany

This amendment is only valid in combination with the following EC Declaration of Conformity (IVDD):

Product Name: Elecsys HBsAg II

Cat. No.:
08814848190

Signed on: 15-Feb-2021

This Amendment confirms the validity of the aforementioned EC Declaration of Conformity (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.

Description of change:
Addition of a new catalogue number 08814848192 for a new package size ("multi pack/maxi pack") of the product Elecsys HBsAg II.

Intended Use:
Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis-B Oberflächenantigen (HBsAg) in Humanserum und -plasma.
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.
Immunoassay for the in vitro qualitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Mannheim, 18 August 2023

Roche Diagnostics GmbH

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

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Dr. Christina Schmid
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EC 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
Authorized Representative:	N/A
Address:	
Single Registration Number:	N/A

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	**Cat. No.**	**Basic UDI-DI**
HCYS	05385415190	761333600077A8
HCYS	06542921190	7613336002009F
HCYS	08057826190	761333600641AH
Homocysteine Calibrator Kit	05385504190	761333600079AC
Homocysteine Control Kit	05142423190	7613336003219U

Risk Class: ☐ *A* ☐ *B* ☒ *C* ☐ *D*

Conformity Route:
☐ *Self-Declaration of Conformity (Class A)*
☒ *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*

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

Mannheim, 16 June 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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Dr. Joachim Hoch
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