

## 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, under the sole responsibility, declares that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Elecsys C-Peptide	03184897190	761333600931AV
Elecsys C-Peptide	03184897214	761333602044A7
Elecsys C-Peptide	07027168190	761333600993BK
Elecsys C-Peptide	07027168214	761333602053A8
C-Peptide CalSet	03184919190	761333600932AX

*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 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. (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, 27 October 2022

Roche Diagnostics GmbH

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

DocuSigned by:  
*Christina Schmid*  
59311CC1CDA8480...

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

*ppa./on behalf of the company*

DocuSigned by:  
*Stefan Scheib*  
FC5EDEC1054B44C...

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

*Contact address:*

Roche Diagnostics GmbH  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

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as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

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Address: Sandhofer Strasse 116  
 68305 Mannheim  
 Germany

Single Registration Number: DE-MF-000006260

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys IgE II	04827031190	761333600657AY
Elecsys IgE II	04827031214	761333602046AB
Elecsys IgE II	07027516190	761333600614AE
Elecsys IgE II	07027516214	761333602057AG
IgE CalSet	11930427122	761333600742AQ

*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 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

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*Other:*  Common Specifications:

*Notified Body (NB) Name:* TÜV Süd Product Service GmbH  
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Product Name	Cat. No.	Basic UDI-DI
Elecsys Insulin	12017547122	761333600744AU
Elecsys Insulin	12017547214	761333602084AK
Elecsys Insulin	07027559190	761333600615AG
Elecsys Insulin	07027559214	761333602058AJ
Insulin CalSet	12017504122	761333600743AS

*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 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

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Mannheim, 27 October 2022

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Single Registration Number: DE-MF-000006260

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Product Name	Cat. No.	Basic UDI-DI
Elecsys total PSA	08791686190	761333600805AP
Elecsys total PSA	08791716190	761333600806AR
Elecsys total PSA	08791732190	761333600807AT
total PSA CalSet II	08838534190	761333600810AG

*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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*NB Ident. No.:* 0123



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

Mannheim, 17 October 2022

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**Single Registration Number:** DE-MF-000006260

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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys FT3 III	09005803190	7613336011329W
Elecsys FT3 III	09005811190	7613336011339Y
Elecsys FT3 III	09005811214	761333602752B9

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

Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and 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>
FT3 III CalSet	09077871190	761333601134A2

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

FT3 III CalSet is used for calibrating the quantitative Elecsys FT3 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:**

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*Other:*  *Common Specifications:*

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*NB Ident. No.:* 0123

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Mannheim, 15 March 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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**Stefan Scheib**  
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Dr. Stefan Scheib  
Global Head of Regulatory Affairs, Core Lab

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**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 FT4 IV	09043276190	761333600839B8
Elecsys FT4 IV	09043284190	761333600909B4
Elecsys FT4 IV	09650547190	761333602872BL

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

Immunoassay for the in vitro quantitative determination of free thyroxine 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
CalSet FT4 IV	09043292190	761333600910AM

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

CalSet FT4 IV is used for calibrating the quantitative Elecsys FT4 IV 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

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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, 29 September 2023


Roche Diagnostics GmbH

i.V./on behalf of the company

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Dr. Bernd Röttinger  
Head of Pre-Market Quality Point of Care

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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



## 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 HBeAg**

Art.-Nr./Cat. No.: **07027427190**

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis B e Antigen (HBeAg) 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 e antigen (HBeAg) in human serum and plasma.  
The electrochemiluminescence immunoassay "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, 21 September 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:  
  
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Ralf Zielenski  
Head Q&R Compliance, PRRC RDG  
Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

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

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

## 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)

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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 HBsAg II**

Art.-Nr./Cat. No.: **08814848190**

Beschreibung/Description: 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.*

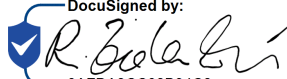
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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, 15 February 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:  
  
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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

ppa./on behalf of the company

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FC5EDEC1054B44C...

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

Kontaktadresse/Contact address: Roche Diagnostics GmbH  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Strasse 116  
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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-HCV II**

Art.-Nr./Cat. No.: **07026889190**

Beschreibung/Description: 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.*

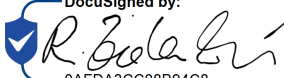
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Mannheim, 10 February 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

ppa./on behalf of the company

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

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

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

**Single Registration Number:** TBD (application filed; confirmation pending)

**Authorized Representative:** N/A  
**Address:**

**Single Registration Number:** N/A

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 IGF-1	07475896190	761333600465AM
Elecsys IGF-1	07475918190	761333600466AP
CalSet IGF-1	07475969190	761333600467AR

**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
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**Other:**  Common Specifications:

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**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, 12 May 2021

Roche Diagnostics GmbH

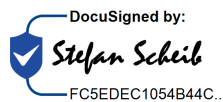
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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

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Dr. Stefan Scheib  
Director Global Regulatory Affairs  
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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys Prolactin II	03203093190	761333600587B4
Elecsys Prolactin II	03203093214	761333600588B6
Elecsys Prolactin II	07027737190	761333600617AL
Elecsys Prolactin II	07027737214	761333602061A7
Prolactin II CalSet	03277356190	761333600591AT

**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)  
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Mannheim, 17 December 2021

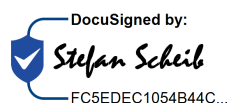
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Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

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

Contact address:

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

## **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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys PTH	11972103122	761333601655B3
Elecsys PTH STAT	04892470190	761333601498BB
Elecsys PTH	07251068190	761333601500A5
CalSet PTH	08243875190	761333601541AK
CalSet PTH STAT	08243930190	761333601543AP
CalSet II PTH	08243891190	761333601542AM

**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



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

Mannheim, 5 July 2021

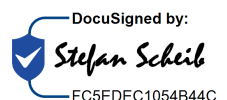
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski  
Head Q&R Compliance, PRRC RDG  
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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:** TBD (application filed; confirmation pending)

**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
Elecsys Testosterone II	08946353190	761333601076AD
Elecsys Testosterone II	08946370190	7613336011319U

**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:

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**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, 24 March 2021

Roche Diagnostics GmbH

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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

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Dr. Stefan Scheib  
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**Single Registration Number:** TBD (application filed; confirmation pending)

**Authorized Representative:** N/A  
**Address:**

**Single Registration Number:** N/A

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 Anti-TPO	06368590190	761333600969BN
Anti-TPO CalSet	06472931190	761333600977BM
Elecsys Anti-TPO	07026935190	761333600988BS

**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

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

Mannheim, 17 May 2021

Roche Diagnostics GmbH

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Dr. Stefan Scheib  
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## **EC Declaration of Conformity**

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

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**Single Registration Number:** TBD (application filed; confirmation pending)

**Authorized Representative:** N/A  
**Address:**

**Single Registration Number:** N/A

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 TSH	08429324190	7613336001129H
Elecsys TSH	08443432190	7613336001139K
TSH CalSet	08443459190	7613336001149M

**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  
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 80339 Munich  
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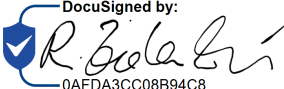
*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 5 February 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

*ppa./on behalf of the company*

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**Authorized Representative:** N/A  
**Address:**

**Single Registration Number:** N/A

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 Vitamin B12 II	07028121190	7613336004029V
Elecsys Vitamin B12 II	07212771190	761333600436AE
Vitamin B12 II CalSet	07212780190	761333600437AG

**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  
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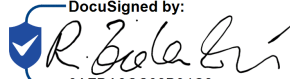


*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 9 April 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

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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 Vitamin D total II	07028148190	7613336004039X
Elecsys Vitamin D total II	07464215190	761333600460AB
PreciControl Vitamin D total II	07464266190	761333600462AF
PreciControl Vitamin D total II	07464266922	761333600463AH
Vitamin D total II CalSet	07464240190	761333600461AD

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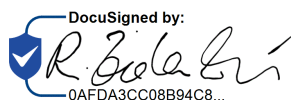
*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 9 April 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

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Ralf Zielenski  
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