

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 Anti-TPO	06368590190	761333600969BN

Intended Use:

Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Anti-TPO CalSet	06472931190	761333600977BM

Intended Use:

Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Anti-TPO	07026935190	761333600988BS

Intended Use:

Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases. 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
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, 26 April 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:

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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 CMV IgG

Art.-Nr./Cat. No.: 04784596190

Beschreibung/Description: Immunologischer in vitro Test zur quantitativen Bestimmung der IgG-Antikörper gegen das Zytomegalievirus in Humanserum und -plasma. Die Ergebnisse dieses Tests dienen als Nachweis für eine abgelaufene oder kürzlich erworbene CMV-Infektion. Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und cobas e Immunoassay-Systemen vorgesehen.
Immunoassay for the in vitro quantitative determination of IgG antibodies to cytomegalovirus in human serum and plasma. Results with this assay are used to indicate past or recent infection with CMV.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and 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 February 2018

Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

i.V. Dr. Manfred Böhm



Dr. Stefan Scheib
Director Global Regulatory Affairs
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Kontaktadresse/Contact address: Roche Diagnostics GmbH
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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 CMV IgM

Art.-Nr./Cat. No.: **04784618190**

Beschreibung/Description: Immunologischer in vitro Test zur qualitativen Bestimmung der IgM-Antikörper gegen das Zytomegalievirus in Humanserum und -plasma. Die Testergebnisse werden zur Unterstützung bei der Diagnose einer kürzlich erworbenen CMV-Infektion verwendet. Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und **cobas e** Immunoassay-Systemen vorgesehen.

Immunoassay for the in vitro qualitative determination of IgM antibodies to cytomegalovirus in human serum and plasma.

Results obtained with this assay are used as an aid in the diagnosis of recent CMV infections.

*The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **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, 23 January 2018

Roche Diagnostics GmbH

ppa./on behalf of the company
ppa. Dr. Beate Bonefeld



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company
i.V. Dr. Manfred Böhm



Dr. Stefan Scheib
Director Global Regulatory Affairs
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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 IgE II	04827031190	761333600657AY
Elecsys IgE II	04827031214	761333602046AB

Intended Use:

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma. Determination of total IgE is useful as an aid in the diagnosis of allergic diseases. The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys IgE II	07027516190	761333600614AE
Elecsys IgE II	07027516214	761333602057AG

Intended Use:

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma. Determination of total IgE is useful as an aid in the diagnosis of allergic diseases. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
IgE CalSet	11930427122	761333600742AQ

Intended Use:

IgE CalSet is used for calibrating the quantitative Elecsys IgE 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

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

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

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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: **PreciControl CMV IgG**

Art.-Nr./Cat. No.: **04784600190**

Beschreibung/Description: PreciControl CMV IgG dient zur Qualitätskontrolle des Elecsys CMV IgG und des Elecsys CMV IgG Avidity Immunoassays auf **cobas e** Immunoassay-Analysern.

*PreciControl CMV IgG is used for quality control of the Elecsys CMV IgG and the Elecsys CMV IgG Avidity immunoassay 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, 26 April 2022

Roche Diagnostics GmbH

ppa./on behalf of the company

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

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Dr. Stefan Scheib
Network Lead Core Lab, Global Regulatory Affairs
Centralised and Point of Care Solutions

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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: **PreciControl CMV IgM**

Art.-Nr./Cat. No.: **04784626190**

Beschreibung/Description: PreciControl CMV IgM dient zur Qualitätskontrolle des Elecsys CMV IgM Immunoassays auf **cobas e** Immunoassay-Analysern.

*PreciControl CMV IgM is used for quality control of the Elecsys CMV IgM immunoassay 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.

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Mannheim, 14 February 2022

Roche Diagnostics GmbH

ppa./on behalf of the company

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Centralised and Point of Care Solutions

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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: **PreciControl Toxo IgG**

Art.-Nr./Cat. No.: **04618823190**

Beschreibung/Description: PreciControl Toxo IgG dient zur Qualitätskontrolle der Elecsys Toxo IgG und Toxo IgG Avidity Immunoassays auf **cobas e** Immunoassay-Analysern.

*PreciControl Toxo IgG is used for quality control of the Elecsys Toxo IgG and Toxo IgG Avidity immunoassays 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, 14 February 2022

Roche Diagnostics GmbH


ppa./on behalf of the company

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

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Dr. Stefan Scheib
Network Lead Core Lab, Global Regulatory Affairs
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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 Toxo IgG

Art.-Nr./Cat. No.: 04618815190

Beschreibung/Description: Immunologischer in vitro Test zur quantitativen Bestimmung der IgG-Antikörper gegen *Toxoplasma gondii* in Humanserum und -plasma. Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und **cobas e** Immunoassay-Systemen vorgesehen.

Immunoassay for the in vitro quantitative determination of IgG antibodies to Toxoplasma gondii in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

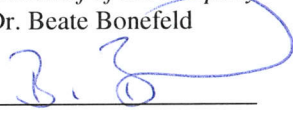
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

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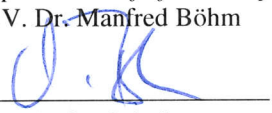
Mannheim, 23 January 2018

Roche Diagnostics GmbH

ppa./on behalf of the company
ppa. Dr. Beate Bonefeld


Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company
i.V. Dr. Manfred Böhm


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

Kontaktadresse/Contact address: Roche Diagnostics GmbH
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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 Toxo IgM	04618858190	761333600291AC

Intended Use:

Immunoassay for the in vitro qualitative determination of IgM antibodies to Toxoplasma gondii 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 Toxo IgM	07028024190	7613336004019T

Intended Use:

Immunoassay for the in vitro qualitative determination of IgM antibodies to Toxoplasma gondii 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
PreciControl Toxo IgM	04618866190	761333600292AE

Intended Use:

PreciControl Toxo IgM is used for quality control of the Elecsys Toxo IgM immunoassay 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, 30 October 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

ppa./on behalf of the company

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Dr. Stefan Scheib
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