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-HBc II**
Art.-Nr./*Cat. No.*:	**09014926190**
Beschreibung/*Description*:	Immunologischer In-vitro-Test zur qualitativen Bestimmung der IgG- und IgM-Antikörper gegen das Hepatitis B-Core-Antigen 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 qualitative determination of IgG and IgM antibodies to the hepatitis B core antigen in human serum and plasma. The **e**lectro**c**hemi**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, 31 May 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A45CC19E27A04F3...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

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

Digitally signed by Lazari Cristina
Date: 2023.02.14 12:25:31 EET
Reason: MoldSign Signature
Location: Moldova

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

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: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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-HBe**
Art.-Nr./*Cat. No.*:	**07026838190**
Beschreibung/*Description*:	Immunologischer In-vitro-Test zur qualitativen Bestimmung von humanen Antikörpern gegen Hepatitis B e Antigen (HBeAg) 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 qualitative determination of human antibodies to the hepatitis B e antigen (HBeAg) in human serum and plasma.* *The **e**lectro**c**hemi**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 February 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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

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

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**lectro**c**hemi**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
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

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

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-HCV II**
Art.-Nr./*Cat. No.*:	**08836981190** **08837031190** **08837058190**
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 **E**lektro**C**hemi**L**umineszenz **I**mmuno**A**ssay "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 **e**lectro**c**hemi**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).

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

Mannheim, 9 February 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

Dr. Stefan Scheib
Network Lead Core Lab, 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

EC Declaration of Conformity

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

Manufacturer:
Address:

Roche Diagnostics GmbH
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-Tg	09004998190	7613336011419X
Elecsys Anti-Tg	09005021190	7613336011429Z
Anti-Tg CalSet	09005030190	761333601143A3

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

NB Ident. No.:

0123

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

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

Mannheim, 7 December 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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

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*:	**Anti-TPO CalSet**
Art.-Nr./*Id. No.*:	**06472931**
Beschreibung/*Description*:	Anti-TPO CalSet wird zur Kalibration des quantitativen Elecsys Anti-TPO Tests auf Elecsys und **cobas e** Immunoassay-Systemen verwendet. *Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and **cobas e** immunoassay analyzers.*

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, 19.09.2013
Roche Diagnostics GmbH

ppa./*on behalf of the company*	i. V./*on behalf of the company*
Dr. M. Thein Head of Quality Roche Professional Diagnostics	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

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

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:*	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-TPO**
Art.-Nr./*Cat. No.*:	**07026935190**
Beschreibung/*Description*:	Immunologischer In-vitro-Test zur quantitativen Bestimmung von Thyreoperoxidase-Antikörper in Humanserum und -plasma. Die Anti-TPO-Bestimmung dient als Hilfsmittel zur Diagnose von autoimmunen Schilddrüsenerkrankungen. 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 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 **e**lectro**c**hemi**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, 24 February 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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

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: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

EC Declaration of Conformity

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

Manufacturer: *Address:*	Roche Diagnostics GmbH 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:	**AssayTip/AssayCup tray**
Cat.-No.:	**05694302001**
Basic UDI-DI:	**761333601957BN**
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: *NB Address:*	*N/A*
NB Ident. No.:	*N/A*

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

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

Mannheim, 23 November 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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

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

Product Name	**Cat. No.**	**Basic UDI-DI**
CleanCell M	04880293190	761333601330A4
CleanCell M	04880293214	761333602614AU

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.

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

Mannheim, 30 May 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

Dr. Stefan Scheib
Network Lead Core Lab, 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

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:*	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*:	**Diluent Universal**
Art.-Nr./*Cat. No.*:	**07299001190**
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-Diagnostika 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, 02 June 2016

Roche Diagnostics GmbH

ppa./*on behalf of the company*

i.V. L. Caugn

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

Dr. Peter Martin
Senior 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

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