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

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
E3965E80F3E840E...

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

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

Contact address:

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

Digitally signed by Lazari Cristina
Date: 2025.12.29 11:19:27 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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*

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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
D-68305 Mannheim

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*

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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
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 Parliament and Council of 27 October 1998
und/*and*
gemäß Änderung des Anhangs II 2015/863/EU der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 31. März 2015
as per amendment of Annex II 2015/863/EU of Directive 2011/65/EU of the European Parliament and Council of 31 March 2015

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

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

Produktname/*Product name*:	**cobas c 111 analyzer**
Art.-Nr./*Cat. No.*:	**04528778001**
Beschreibung/*Description*:	*In-vitro* diagnostic analyzer performing clinical chemistry and specific protein tests. Analytes are measured photometrically or turbidimetrically.

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-Diagnostika (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).

und/*and* Ab Serien-Nr./*Starting with Serial No.:*	**16000**

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 2011/65/EU inklusive Änderung des Anhangs II 2015/863/EU vom 31 März 2015 betreffend Beschränkung der Verwendung bestimmter gefährlicher Stoffe gemäss Anhang II (Blei, Quecksilber, Cadmium, Sechswertiges Chrom, Polybromierte Biphenyle, Polybromierte Diphenylether, Di(2-ethylhexyl)phthalat (DEHP), Butylbenzylphthalat (BBP), Dibutylphthalat (DBP) und Diisobutylphthalat (DIBP)) in Elektro- und Elektronikgeräten (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

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

to which this declaration relates fulfills the requirements of Directive 2011/65/EU including amendment of Annex II 2015/863/EU of 31 March 2015 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls, polybrominated diphenyl ethers, bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP)) in electrical and electronic equipment (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 July 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

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

HITACHI

EU Declaration of Conformity

Manufacturer:	Hitachi High-Tech Corporation
Address:	1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN
Single Registration Number:	JP-MF-000016991
European Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116, 68305 Mannheim, Germany

Product name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas c 311 analyzer	761333601323A7	04826876001	Class A

We, Hitachi High-Tech Corporation, declare under our sole responsibility that the above listed device(s) is/are in conformity with the following European Union harmonisation legislation:

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

Intended use/purpose:	The cobas c 311 analyzer is an automated analyzer including software, intended for running qualitative, semi-quantitative and quantitative clinical chemistry assays as well as ion selective measurements.
Notified Body's name/ number (if applicable):	Not applicable
IVDR conformity assessment procedures:	Annex II and III of REGULATION (EU) 2017/746 (Class A)
Applied standards:	See Appendix I
Starting Serial No.:	See Appendix II

on behalf of the company

Date: 29. Jun. 2022

Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dep't
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date: 29 Jun 2022

Yoshitaka Kodama
General Manager
Life & Medical Systems Center
Life & Medical Systems Business Div.
Analytical & Medical Solution Business Group
Hitachi High-Tech Corporation

Contact address:
Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN

Appendix I
List of applied standards:

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Standard number, year	Name of applied standard
EN ISO 13485: 2016	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 62304: 2006 / AC: 2008	Medical device software - Software life-cycle processes
EN 62366: 2008 + A1:2015	Medical devices - Application of usability engineering to medical devices
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6: 2012/ EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Standard number, year	Name of applied standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Appendix II
List of applicable product name and serial number

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Product name or component name	Starting serial number
cobas c 311 analyzer	From 2298-01 onward

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Product name or component name	Starting serial number
cobas c 311 analyzer	From 2051-01 onward

End of the document

HITACHI

EU Declaration of Conformity

Manufacturer:	Hitachi High-Tech Corporation
Address:	1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN
Single Registration Number:	Not available yet
European Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116, 68305 Mannheim, Germany

Product name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas e 411 analyzer (rack system)	7613336013209Z	04775201001	Class A
cobas e 411 analyzer (disk system)	761333601321A3	04775279001	Class A

We, Hitachi High-Tech Corporation, declare under our sole responsibility that the above listed device(s) is/are in conformity with the following European Union harmonisation legislation:

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

Intended use/purpose:	The cobas e 411 analyzer (rack system) and the cobas e 411 analyzer (disk system) are automated analyzers including software, intended for running qualitative, semi-quantitative and quantitative immunochemistry assays.
Notified Body's name/ number (if applicable):	Not applicable
IVDR conformity assessment procedures:	Annex II and III of REGULATION (EU) 2017/746 (Class A)
Applied standards:	See Appendix I
Starting Serial No.:	See Appendix II

on behalf of the company

Date: 7. July. 2021

Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dep't
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date: 7th July 2021

Yoshitaka Kodama
General Manager
Life & Medical Systems Center
Life & Medical Systems Business Div.
Analytical & Medical Solution Business Group
Hitachi High-Tech Corporation

Contact address:
Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN

Appendix I
List of applied standards:

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Standard number, year	Name of applied standard
EN ISO 13485: 2016	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 62304: 2006 / AC: 2008	Medical device software - Software life-cycle processes
EN 62366: 2008 + A1:2015	Medical devices - Application of usability engineering to medical devices
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6: 2012/ EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Standard number, year	Name of applied standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Appendix II
List of applicable product name and serial number

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Product name or component name	Starting serial number
cobas e 411 analyzer (rack system)	From 8901-01 onward
cobas e 411 analyzer (disk system)	From 8901-01 onward

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Product name or component name	Starting serial number
cobas e 411 analyzer (rack system)	From 8845-03 onward
cobas e 411 analyzer (disk system)	From 8845-01 onward

End of the document

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*

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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
D-68305 Mannheim

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*

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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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

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*

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

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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*

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, 16 June 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

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

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Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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