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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).

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Location: Moldova

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

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Mannheim, 9 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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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 HIV Duo**
Art.-Nr./*Cat. No.*:	**08836973190**
Beschreibung/*Description*:	Immunologischer In-vitro-Test zur qualitativen Bestimmung von HIV-1 p24-Antigen und Antikörpern gegen HIV-1, einschließlich Gruppe O, und HIV-2 in Humanserum und -plasma. Die Einzelergebnisse (HIV Ag und Anti-HIV) dienen als Hilfe bei der Auswahl des Bestätigungsalgorithmus für reaktive Proben. 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 HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma. The subresults (HIV Ag and anti-HIV) are intended as an aid in the selection of the confirmation algorithm for reactive samples.* *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

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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Mannheim, 4 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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Stefan Scheib
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Dr. Stefan Scheib
Director Global Regulatory Affairs
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Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
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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 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 **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 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, 15 February 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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Head of Quality
Centralised and Point of Care Solutions

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Dr. Stefan Scheib
Director Global Regulatory Affairs
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Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
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Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

HITACHI

EU Declaration of Conformity

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

Product Name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas e 801 analytical unit	761333601561AR	08454345001	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
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Intended use/purpose:	The cobas e 801 analytical unit is a configurable device used for immunoassay analysis in the cobas 8000 modular analyzer series for in-vitro determinations. Additionally, it is a configurable device used for immunoassay analysis in the cobas pro integrated solutions for in-vitro determinations.
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: 27. 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: 27 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 62366: 2008 (for cobas 8000) EN 62366: 2008 + A1 2015 (for cobas pro)	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

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Standard number, year	Name of applied standard
EN 300 330 V2.1.1	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
IEC61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62479:2010:	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V1.9.2:	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1:	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

Appendix II
List of applicable product name and starting 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 801 analytical unit	From 2201-01 to 31Z9-10, From 4201-01 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 801 analytical unit	From 2070-01 onward

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Product name or component name	Starting serial number
cobas e 801 analytical unit	From 1801-01 onward

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EU Declaration of Conformity

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

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-MF-000006260

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys Syphilis	09014977190	761333601171A8
Elecsys Syphilis	09015035190	761333601172AA
Elecsys Syphilis	09015051190	761333601173AC

Intended Use:
Immunoassay for the in vitro qualitative determination of total antibodies to Treponema pallidum in human serum and plasma. The test is intended as an aid in the diagnosis of syphilis infection.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
PreciControl Syphilis	06923364190	761333601452AK

Intended Use:
PreciControl Syphilis is used for quality control of the Elecsys Syphilis 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

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

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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	☐ 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.: *V10 010283 0641*
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): *): V70 010283 0695*
Other:	☒ Common Specifications: *(EU) 2022/1107 of 4 July 2022*
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, 3 June 2024

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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Global Head of Regulatory Affairs, Core Lab

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