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 Anhang VI der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
as per Annex VI of Directive 2011/65/EU of the European Parliament and Council of 8 June 2011

Hersteller/*Manufacturer*:
Hitachi High-Technologies Corporation
1-24-14 Nishi-Shimbashi, Minato-ku
Tokyo 105-8717
Japan

Authorized Representative:
Roche Diagnostics GmbH
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*: **Na Electrode**

Art.-Nr./*Id. No.*: **10825468001**

Beschreibung/*Description*: Ionen-selektive Elektrode in Kombination mit ISE Modulen der Roche/Hitachi Analysenautomaten zur quantitative Bestimmung von Natrium in Serum, Plasma oder Urin.
Ion-selective electrode to be used with ISE modules of Roche/Hitachi analyzer for quantitative determination of sodium in serum, plasma or urine.

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).

und/*and*
Ab Serien-Nr./*Starting with Serial No.*: Q5700

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

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 2011/65/EU inklusive Artikel 4 des Europäischen Parlaments und des Rates vom 8. Juni 2011 betreffend Beschränkung der Verwendung bestimmter gefährlicher Stoffe gemäss Anhang II (Blei, Quecksilber, Cadmium, Sechswertiges Chrom, Polybromierte Biphenyle and Polybromierte Diphenylether) in Elektro- und Elektronikgeräten (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
to which this declaration relates fulfills the requirements of Directive 2011/65/EU including Article 4 of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls and polybrominated diphenyl ethers) 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, 27 July 2016

Roche Diagnostics GmbH

ppa./*on behalf of the company*

i.V.

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
68305 Mannheim
Germany

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

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*:	**NACL** Diluent NaCl 9 %
Art.-Nr./*Cat. No.*:	**08063494190**
Beschreibung/*Description*:	Diluent NaCl 9 % dient als Probendiluens, das zusammen mit Testreagenzien auf **cobas c** Systemen eingesetzt wird. *Diluent NaCl 9 % is used as a sample diluent in conjunction with assay reagents on **cobas c** systems.*

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, 7 November 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*

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 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*:	**NAOHD**
Art.-Nr./*Cat. No.*:	**08063451190**
Beschreibung/*Description*:	Waschlösung für Reagenznadeln und Küvetten bei Roche/Hitachi **cobas c** Systemen. *Wash solution for reagent probes and reaction cells on Roche/Hitachi **cobas c** systems.*

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, 7 November 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*

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

Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
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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 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*:	**PreciControl HbA1c norm**
Art.-Nr./*Id. No.*:	**05479207** **05991323**
Beschreibung/*Description*:	PreciControl HbA1c norm dient zur Qualitätskontrolle und wird zur Richtigkeits- und Präzisionskontrolle von quantitativen Methoden, wie in den Werteblättern angegeben, eingesetzt. *PreciControl HbA1c norm is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.*

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, 11.11.2010
Roche Diagnostics GmbH

ppa./*on behalf of the company*

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

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

Annerose Schenkel
Head of Quality Control Mannheim
Roche Diagnostics Global Operations

Kontaktadresse/*Contact address*: Roche Professional Diagnostics
Abt./*Dept.* Global Regulatory Affairs
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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

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*:	**PreciControl HbA1c path**
Art.-Nr./*Id. No.*:	**05912504** **05991331**
Beschreibung/*Description*:	PreciControl HbA1c path dient zur Qualitätskontrolle und wird zur Richtigkeits- und Präzisionskontrolle von quantitativen Methoden, wie in den Werteblättern angegeben, eingesetzt. *PreciControl HbA1c path is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.*

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, 11.11.2010
Roche Diagnostics GmbH

ppa./*on behalf of the company*

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

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

Annerose Schenkel
Head of Quality Control Mannheim
Roche Diagnostics Global Operations

Kontaktadresse/*Contact address*: Roche Professional Diagnostics
Abt./*Dept.* Global Regulatory Affairs
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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

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*:	**PreciControl ClinChem Multi 1**
Art.-Nr./*Id. No.*:	**05947626, 05117003, 05117208**
Beschreibung/*Description*:	PreciControl ClinChem Multi 1 wird in der Qualitätskontrolle zur Richtigkeits- und Präzisionskontrolle von den in den Werteblättern angegebenen quantitativen Methoden eingesetzt. *PreciControl ClinChem Multi 1 is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.*

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, 13. August 2010

Roche Diagnostics GmbH

ppa./*on behalf of the company*	i. V./*on behalf of the company*
Dr. M. Thein Head of Quality & Regulatory Management Professional Diagnostics	A. Schenkel Head of Quality Control Professional Diagnostics

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; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

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*:	**PreciControl ClinChem Multi 2**
Art.-Nr./*Id. No.*:	**05947774, 05117216, 05117291**
Beschreibung/*Description*:	PreciControl ClinChem Multi 2 wird in der Qualitätskontrolle zur Richtigkeits- und Präzisionskontrolle von den in den Werteblättern angegebenen quantitativen Methoden eingesetzt. *PreciControl ClinChem Multi i2 is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.*

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, 13. August 2010

Roche Diagnostics GmbH

ppa./*on behalf of the company*

Dr. M. Thein
Head of Quality & Regulatory Management
Professional Diagnostics

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

A. Schenkel
Head of Quality Control
Professional Diagnostics

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; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

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
RF-II	05480167190	7613336001019C
RF-II	08058628190	7613336000149G
RF-II	08058628214	761333603207AJ

Intended Use:
In vitro test for the quantitative determination of Rheumatoid Factors (RF-II) in human serum and plasma on cobas c systems. Measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Product Name	Cat. No.	Basic UDI-DI
RF-II	20764574322	761333600158A9

Intended Use:
In vitro test for the quantitative determination of Rheumatoid Factors (RF-II) in human serum and plasma on cobas c and COBAS INTEGRA systems. Measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Product Name	Cat. No.	Basic UDI-DI
RF Control Set	03005496122	7613336001049J

Intended Use:
RF Control Set is for use in quality control by monitoring accuracy and precision for the quantitative method as specified in the value sheets.

Product Name	Cat. No.	Basic UDI-DI
Preciset RF	12172828322	761333600147A4

Intended Use:
Preciset RF is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

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; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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, 19 September 2025

Roche Diagnostics GmbH

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

DocuSigned by:
Klaus Riebel
5E57330EEFE04C4...

Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

Mannheim, 19. September 2025

Roche Diagnostics GmbH

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 Anhang VI der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
as per Annex VI of Directive 2011/65/EU of the European Parliament and Council of 8 June 2011

Hersteller/*Manufacturer*:
Hitachi High-Technologies Corporation
1-24-14 Nishi-Shimbashi, Minato-ku
Tokyo 105-8717
Japan

Authorized Representative:
Roche Diagnostics GmbH
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*: **REF Electrode**

Art.-Nr./*Id. No.*: **03149501001**

Beschreibung/*Description*: ISE Referenz Elektrode zur Verwendung mit ISE Modulen der Roche/Hitachi Analysenautomaten.
ISE reference electrode to be used with ISE modules of Roche/Hitachi analyzer.

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).

und/*and*
Ab Serien-Nr./*Starting with Serial No.*: L9600

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 2011/65/EU inklusive Artikel 4 des Europäischen Parlaments und des Rates vom 8. Juni 2011 betreffend Beschränkung der Verwendung bestimmter gefährlicher Stoffe gemäss Anhang II (Blei, Quecksilber, Cadmium, Sechswertiges Chrom, Polybromierte Biphenyle and Polybromierte Diphenylether) 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; 68305 Mannheim; Germany, Telefon +49-621-759-0; Telefax +49-621-759-2890

to which this declaration relates fulfills the requirements of Directive 2011/65/EU including Article 4 of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls and polybrominated diphenyl ethers) 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, 27 July 2016

Roche Diagnostics GmbH

ppa./*on behalf of the company*

i. V.

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
68305 Mannheim
Germany

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

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
RF-II	05480167190	7613336001019C
RF-II	08058628190	7613336000149G
RF-II	08058628214	761333603207AJ

Intended Use:
In vitro test for the quantitative determination of Rheumatoid Factors (RF-II) in human serum and plasma on cobas c systems. Measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Product Name	Cat. No.	Basic UDI-DI
RF-II	20764574322	761333600158A9

Intended Use:
In vitro test for the quantitative determination of Rheumatoid Factors (RF-II) in human serum and plasma on cobas c and COBAS INTEGRA systems. Measurements may be used as an aid in the diagnosis of rheumatoid arthritis.

Product Name	Cat. No.	Basic UDI-DI
RF Control Set	03005496122	7613336001049J

Intended Use:
RF Control Set is for use in quality control by monitoring accuracy and precision for the quantitative method as specified in the value sheets.

Product Name	Cat. No.	Basic UDI-DI
Preciset RF	12172828322	761333600147A4

Intended Use:
Preciset RF is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

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; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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, 19 September 2025

Roche Diagnostics GmbH

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

DocuSigned by:
Klaus Riebel
5E57330EEFE04C4...

Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

Mannheim, 19. September 2025

Roche Diagnostics GmbH

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

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:	**Sample Cup**
Cat.-No.:	**10394246001**
Basic UDI-DI:	**761333601962BF**
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

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

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

Mannheim, 22 November 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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

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

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Joachim Hoch
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Dr. Joachim Hoch
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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*:	**SCCS** Special Cell Cleaning Solution
Art.-Nr./*Cat. No.*:	**08463093190**
Beschreibung/*Description*:	Waschlösung für Küvetten bei Roche/Hitachi **cobas c** Systemen. *Wash solution for reaction cells on Roche/Hitachi **cobas c** systems.*

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, 7 November 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*

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

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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*:	**SMS**
Art.-Nr./*Cat. No.*:	**08063478190**
Beschreibung/*Description*:	Waschlösung für Reagenznadeln und Küvetten bei Roche/Hitachi **cobas c** Systemen. *Wash solution for reagent probes and reaction cells on Roche/Hitachi **cobas c** systems.*

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, 6 June 2019

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*

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

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

Produktname/*Product name*:	**TP2** Total Protein Gen.2
Art.-Nr./*Cat. No.*:	**08058652190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Gesamtprotein in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of total protein in human serum and plasma on Roche/Hitachi **cobas c** systems.*

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, 22 October 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*

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

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

Produktname/*Product name*:	**TRIGL** Triglycerides
Art.-Nr./*Cat. No.*:	**08058687190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Triglyceriden in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of triglycerides in human serum and plasma on Roche/Hitachi **cobas c** systems.*

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, 22 October 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*

Dr. Stefan Scheib
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Roche Diagnostics GmbH declares that the product/the product line

Produktname/*Product name*:	**UA2** Uric Acid ver.2
Art.-Nr./*Cat. No.*:	**08058750190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Harnsäure in Humanserum, -plasma und -urin mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of uric acid in human serum, plasma and urine on Roche/Hitachi **cobas c** systems.*

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, 22 October 2018

Roche Diagnostics GmbH

ppa./*on behalf of the company*

Ralf Zielenski
Head of Quality
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ppa./*on behalf of the company*

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

Produktname/*Product name*:	**UREAL** Urea/BUN
Art.-Nr./*Cat. No.*:	**08058806190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Harnstoff/Harnstoff-Stickstoff in Humanserum, -plasma und -urin mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of urea/urea nitrogen in human serum, plasma and urine on Roche/Hitachi **cobas c** systems.*

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, 22 October 2018

Roche Diagnostics GmbH

ppa./*on behalf of the company*

Ralf Zielenski
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Dr. Stefan Scheib
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