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*:
Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku
Tokyo 105-6409
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*: **Reaction Cell for c 311**

Art.-Nr./*Id. No.*: **04555040001**

Beschreibung/*Description*: Specific reaction cell for analysis for in in vitro material on the cobas c 311 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).

Mannheim, 2 November 2020

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*
i.V. Dr. Joachim Hoch

DocuSigned by:
Joachim Hoch
18F3891ABF554FF...

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

Digitally signed by Lazari Cristina
Date: 2023.10.31 16:14:17 EET
Reason: MoldSign Signature
Location: Moldova

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 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
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68305 Mannheim
Germany

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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**
RF Control Set	03005496122	7613336001049J
RF-II	05480167190	7613336001019C
RF-II	08058628190	7613336000149G
Preciset RF	12172828322	761333600147A4
RF-II	20764574322	761333600158A9

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, 27 July 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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Ralf Zielenski
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Ralf Zielenski
Head Q&R Compliance, PRRC RDG
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i.V./*on behalf of the company*

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Director Global Regulatory Affairs
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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**
Sample Cleaner 1	04708725190	761333601305A5
CLEAN	04774248190	761333601319AG
Sample Cleaner 1	05352991190	761333601362AH
CLEAN	20764337322	761333601668BC

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, 26 August 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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Ralf Zielenski
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Ralf Zielenski
Head Q&R Compliance, PRRC RDG
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i.V./*on behalf of the company*

DocuSigned by:
Joachim Hoch
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Dr. Joachim Hoch
Director Global Regulatory Affairs
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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**
Sample Cup	10394246001	761333601962BF

Intended Use:
The Sample Cup is an IVD accessory intended to be used with the following systems:
▪ COBAS INTEGRA® 400 plus analyzer
▪ MODULAR PRE-ANALYTICS EVO
▪ cobas c 111 analyzer
▪ cobas c 303 analytical unit
▪ cobas c 311 analyzer
▪ cobas e 402 analytical unit
▪ cobas e 411 analyzer
▪ cobas c 501 module
▪ cobas c 502 module
▪ cobas c 503 analytical unit
▪ cobas e 601 module
▪ cobas e 602 module
▪ cobas c 701 module
▪ cobas c 702 module
▪ cobas e 801 module
▪ cobas e 801 analytical unit
▪ cobas 8000 ISE 900 module
▪ cobas 8000 ISE 1800 module
▪ cobas pro ISE analytical unit
For professional use only.

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.:* ☐ *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*

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

Mannheim, 19 June 2023

Roche Diagnostics GmbH

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

DocuSigned by:
Christina Schmid
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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:

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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**
SMS	04489225190	761333601270AB
SMS	05172136190	761333601355AL
SMS	05172136214	761333601356AN
SMS	08063478190	761333601535AQ

Intended Use:
Wash solution for reagent probes and reaction cells on cobas c systems.

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*

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, 10 August 2023

Roche Diagnostics GmbH

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

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

ppa./*on behalf of the company*

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joachim hoch
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Dr. Joachim Hoch
Subchapter Lead Global Regulatory Affairs

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
TP2	03183734190	7613336002079V

Intended Use:
In vitro test for the quantitative determination of total protein in human serum and plasma on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
TP2	04657586190	761333600297AQ

Intended Use:
In vitro test for the quantitative determination of total protein in human serum and plasma on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
TP2	05171385190	7613336000449R
TP2	05171385214	761333600724AN
TP2	08058652190	7613336000169L

Intended Use:
In vitro test for the quantitative determination of total protein in human serum and plasma on cobas c systems.

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, 9 August 2023

Roche Diagnostics GmbH

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

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

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

DocuSigned by:
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Dr. Joachim Hoch
Subchapter Lead Global Regulatory Affairs

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
TRIGL	04657594190	761333600298AS

Intended Use:
In vitro test for the quantitative determination of triglycerides in human serum and plasma on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
TRIGL	05171407190	761333600049A3
TRIGL	08058687190	7613336000199S
TRIGL	05171407214	761333600726AS

Intended Use:
In vitro test for the quantitative determination of triglycerides in human serum and plasma on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
TRIGL	20767107322	761333600168AC

Intended Use:
In vitro test for the quantitative determination of triglycerides in human serum and plasma on cobas c and COBAS INTEGRA systems.

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, 18 October 2023

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Röttinger
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Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

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

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
UA2	03183807190	7613336002109J

Intended Use:
In vitro test for the quantitative determination of uric acid in human serum, plasma and urine on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
UA2	04657608190	761333600299AU

Intended Use:
In vitro test for the quantitative determination of uric acid in serum, plasma and urine on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
UA2	05171857190	7613336000519N
UA2	05171857214	761333600728AW
UA2	08058750190	7613336000219D

Intended Use:
In vitro test for the quantitative determination of uric acid in human serum, plasma and urine on cobas c systems.

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, 20 October 2023

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Röttinger
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Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

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

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**
UREAL	04460715190	761333600264A9
UREAL	04657616190	7613336003009L
UREAL	05171873190	7613336000539S
UREAL	08058806190	7613336000249K
UREAL	05171873214	761333600958BH

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

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, 21 June 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

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Ralf Zielenski
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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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