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
ECO-D	05422485190	761333601366AR

Intended Use:
EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c 311 systems.

Product Name	Cat. No.	Basic UDI-DI
ECO-D	05907543190	761333601389B5
ECO-D	05907543214	761333601390AN
ECO-D	06544410190	761333601435AK
ECO-D	08063354190	761333601533AL

Intended Use:
EcoTergent is an additive to the reaction bath to reduce surface tension 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:*

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

Notified Body (NB) Name: *N/A*
NB Address:

NB Ident. No.: *N/A*

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

Mannheim, 11 September 2023

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Röttinger
00ABEBB0E89341C...

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

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:	*TBD (application filed; confirmation pending)*
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**
GGT-2	03002721122	7613336001029E
GGT-2	05168775190	7613336000229F
GGT-2	05168775214	7613336000259M
GGT-2	05401461190	761333600083A3
GGT-2	08057796190	761333600525AE

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, 20 April 2021

Roche Diagnostics GmbH

DocuSigned by:
Joachim Hoch
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ppa./*on behalf of the company*

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

DocuSigned by:
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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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

EC Declaration of Conformity

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

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-MF-000006260
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**
GLUC3	04404483190	761333600263A7
GLUC3	05168791190	7613336000279R
GLUC3	05168791214	761333600719AV
GLUC3	08057800190	761333600526AG

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, 21 June 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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

EC Declaration of Conformity

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

Manufacturer:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	*TBD (application filed; confirmation pending)*
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**
HDLC4	07528566190	761333600469AV
HDLC4	07528582190	761333600470AE
HDLC4	07528582214	761333600471AG
HDLC4	07528604190	761333600472AJ
HDLC4	08057877190	761333600527AJ

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, 7 May 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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

EC Declaration of Conformity

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

Manufacturer:
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**
IRON2	03183696122	7613336002069T
IRON2	05169291190	7613336000309E
IRON2	05169291214	7613336000329J
IRON2	05401658190	761333600088AD
IRON2	08057931190	761333600531A9

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.

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

Mannheim, 12 October 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
Centralised and Point of Care Solutions

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:
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**
ISE Cleaning Solution / Elecsys SysClean	11298500316	761333601595BA

Intended Use:
For the cleaning of ISE units on Roche/Hitachi analyzers.
For the cleaning of Elecsys and 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*

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

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

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

Mannheim, 11 July 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
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Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

Contact address:

Roche Diagnostics GmbH
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D-68305 Mannheim

EC Declaration of Conformity

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

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

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

Product Name	**Cat. No.**	**Basic UDI-DI**
ISE Diluent Gen.2	04522630190	761333601279AV
ISE Diluent Gen.2	04880480190	761333601333AA

Risk Class: ☒ *A* ☐ *B* ☐ *C* ☐ *D*

Conformity Route:
☒ *Self-Declaration of Conformity (Class A)*
☐ *Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)*
☐ *Technical Documentation Assessment Class B/C – Annex IX*
☐ *Technical Documentation Assessment Class D – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX*
☐ *Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX*

Certificates:
☐ *EU QM Certificate No.:*
☐ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):*

Other: ☐ *Common Specifications:*

Notified Body (NB) Name: *N/A*
NB Address:

NB Ident. No.: *N/A*

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

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

Mannheim, 12 October 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*

DocuSigned by:
Joachim Hoch
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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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

EC Declaration of Conformity

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

Manufacturer:
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**
ISE Internal Standard Gen.2	04522320190	761333600651AL
ISE Internal Standard Gen.2	04880455190	761333600663AT
ISE Reference Electrolyte	10820652216	761333600706AL
ISE Reference Electrolyte	11360981216	761333600718AT
ISE Reference Electrolyte	08392013190	761333600687B9
ISE Standard High	11183982216	761333600711AD
ISE Standard Low	11183974216	761333600709AS

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*

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, 5 November 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

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

DocuSigned by:
Joachim Hoch
18F3891ABF554FF...

Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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

EG-Konformitätserklärung/*EC Declaration of Conformity*

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European 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*: **K Electrode**

Art.-Nr./*Id. No.*: **10825441001**

Beschreibung/*Description*: Ionen-selektive Elektrode in Kombination mit ISE Modulen der Roche/Hitachi Analysenautomaten zur quantitative Bestimmung von Kalium in Serum, Plasma oder Urin.
Ion-selective electrode to be used with ISE modules of Roche/Hitachi analyzer for quantitative determination of potassium 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.*: Y4300

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
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68305 Mannheim
Germany

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