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*:	**ECO-D** EcoTergent
Art.-Nr./*Cat. No.*:	**08063354190**
Beschreibung/*Description*:	EcoTergent ist ein Zusatzmittel für das Reaktionsbad zur Verminderung von Oberflächenspannung bei **cobas c** Systemen. *EcoTergent is an additive to the reaction bath to reduce surface tension 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

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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*:	**GGT-2** γ-Glutamyltransferase ver.2 - Standardized against IFCC / Szasz
Art.-Nr./*Cat. No.*:	**08057796190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung der γ-Glutamyltransferase (GGT) in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of γ-glutamyltransferase (GGT) 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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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*:	**GLUC3** Glucose HK
Art.-Nr./*Cat. No.*:	**08057800190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Glucose in Humanserum, -plasma, -urin und -liquor mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of glucose in human serum, plasma, urine and CSF 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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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*:	**HDLC4** HDL-Cholesterol Gen.4
Art.-Nr./*Cat. No.*:	**08057877190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung der HDL-Cholesterinkonzentration in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro diagnostic test for the quantitative determination of the HDL-cholesterol concentration 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
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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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*:	**IRON2** Iron Gen.2
Art.-Nr./*Cat. No.*:	**08057931190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Eisen in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of iron 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
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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:	**ISE Cleaning Solution / Elecsys SysClean**
Art.-Nr./*Cat. No.*:	**11298500316**
Beschreibung/*Description*:	Zur Reinigung von ISE-Einheiten in Geräten von Roche/Hitachi. Zur Reinigung von Elecsys und **cobas e** Immunoassay-Systemen. *For the cleaning of ISE units on Roche/Hitachi analyzers.* *For the cleaning of Elecsys and **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.
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Mannheim, 16 January 2017

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. Peter Martin
Senior 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*:	**ISE Deproteinizer**
Art.-Nr./*Cat. No.*:	**20763071122**
Beschreibung/*Description*:	ISE Deproteinizer ist eine Reinigungslösung zur Verwendung mit COBAS INTEGRA und **cobas c** 111 ISE Modulen zur Reinigung von ionenselektiven Elektronen und zur Verwendung mit **cobas c** Systemen zur Reinigung des ISE-Fließwegs. *ISE Deproteinizer is a cleaning solution intended for use with the COBAS INTEGRA and **cobas c** 111 ISE modules for cleaning the ionselective electrodes and intended for use with **cobas c** systems for cleaning the ISE flow path.*

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 November 2019

Roche Diagnostics GmbH

ppa./*on behalf of the company*
ppa. Dr. Lydia Langen

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

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

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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*:	**ISE Diluent Gen. 2**
Art.-Nr./*Id. No.*:	**04880480**
Beschreibung/*Description 1*:	Zusatzreagenz für Roche/Hitachi Systeme. *Auxiliary reagent for Roche/Hitachi systems*
Beschreibung/*Description 2*:	Zusatzreagenz für Roche/Hitachi **cobas** c Systeme. *Auxiliary reagent for Roche/Hitachi **cobas** c systems*

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, 25.08.2009
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

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HRB 3962
Aufsichtsrat:
Dr. Severin Schwan, Vorsitzender

Geschäftsführung:
Thomas Schmid, Sprecher
Jürgen Redmann,
Peter-Claus Schiller,
Prof. Dr. Dr. Klaus Strein,
Franz T. Walt

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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*:	**ISE Internal Standard Gen. 2**
Art.-Nr./*Id. No.*:	**04880455**
Beschreibung/*Description 1*:	Zusatzreagenz für Roche/Hitachi Systeme. *Auxiliary reagent for Roche/Hitachi systems*
Beschreibung/*Description 2*:.	Zusatzreagenz für Roche/Hitachi **cobas c** Systeme. *Auxiliary reagent for Roche/Hitachi **cobas c** systems*

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, 25.08.2009
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

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Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/*Product name*:	**ISE Reference Electrolyte**
Art.-Nr./*Id. No.*:	**10820652**
Beschreibung/*Description 1*:	Zusatzreagenz für Roche/Hitachi Systeme. *Auxiliary reagent for Roche/Hitachi systems*
Beschreibung/*Description 2*:	Zusatzreagenz für Roche/Hitachi **cobas c** Systeme. *Auxiliary reagent for Roche/Hitachi **cobas c** systems*

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, 25.08.2009
Roche Diagnostics GmbH
ppa./*on behalf of the company*

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

i.V. Gabriele Hebl

Dr. M. Thein
Head of Quality & Regulatory Management
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A. Schenkel
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Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/*Product name*:	**ISE Standard Low**
Art.-Nr./*Id. No.*:	11183974
Beschreibung/*Description (1)*:	Das ISE-Modul der Roche/Hitachi **cobas c** Systeme dient zur quantitativen Bestimmung von Natrium, Kalium und Chlorid in Serum, Plasma oder Urin mittels ionenselektiver Elektroden. *The ISE module of the Roche/Hitachi **cobas c** systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma or urine using ion-selective electrodes.*
Beschreibung/*Description (2)*:	Zur Kalibration von ionenselektiven Elektroden auf Roche/Hitachi-Geräten. *For use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.*

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, 27.06.2006

Roche Diagnostics GmbH

ppa./*on behalf of the company*

Dr. M. Thein
Head of Quality Management & Regulatory Affairs
Centralized Diagnostics

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

A. Schenkel
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Roche

Diagnostics

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Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/*Product name*:	**ISE Standard High**
Art.-Nr./*Id. No.*:	11183982
Beschreibung/*Description (1)*:	Das ISE-Modul der Roche/Hitachi **cobas c** Systeme dient zur quantitativen Bestimmung von Natrium, Kalium und Chlorid in Serum, Plasma oder Urin mittels ionenselektiver Elektroden. *The ISE module of the Roche/Hitachi **cobas c** systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma or urine using ion-selective electrodes.*
Beschreibung/*Description (2)*:	Zur Kalibration von ionenselektiven Elektroden auf Roche/Hitachi-Geräten. *For use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers.*

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.
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Mannheim, 27.06.2006
Roche Diagnostics GmbH

ppa./*on behalf of the company*

Dr. M. Thein
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Centralized Diagnostics

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

A. Schenkel
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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 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
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
LDHI2	03004732122	7613336001039G

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

Product Name	Cat. No.	Basic UDI-DI
LDHI2	05401674190	761333600089AF

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

Product Name	Cat. No.	Basic UDI-DI
LDHI2	05169330190	7613336000369S
LDHI2	05169330214	761333600722AJ
LDHI2	08057958190	761333600532AB
LDHI2	08057958214	761333602613AS

Intended Use:
In vitro test for the quantitative determination of lactate dehydrogenase 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)

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

	☒ 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, 6 December 2024

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

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 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*:	**LDLC3** LDL-Cholesterol Gen.3
Art.-Nr./*Cat. No.*:	**08057966190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von LDL-Cholesterin in Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of LDL-cholesterol 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, 16 November 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

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

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
LIPC	07041918190	761333600407A7
LIPC	08057982190	7613336000049D

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

Product Name	Cat. No.	Basic UDI-DI
LIPC	03029590322	7613336002019H

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

Product Name	Cat. No.	Basic UDI-DI
LIPC	05401704190	7613336000909Y

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

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

	☐ 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, 12 August 2024

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
485913ABEB04408...

Dr. Peer Lorenz
Site Quality Head / Network Lead, Mannheim

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 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*:	**MG2** Magnesium Gen.2
Art.-Nr./*Cat. No.*:	**08058016190**
Beschreibung/*Description*:	In-vitro-Test zur quantitativen Bestimmung von Magnesium in Humanserum, -plasma und -urin mit Roche/Hitachi **cobas c** Systemen. *In vitro test for the quantitative determination of magnesium 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.
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
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

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