

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

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.*

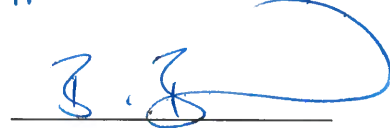
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und
des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der
Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
*to which 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

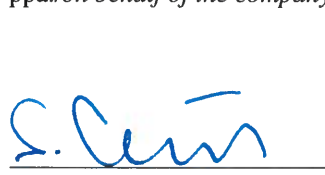
ppa./on behalf of the company

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

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

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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: **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
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Mannheim, 22 October 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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: **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
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Mannheim, 22 October 2018

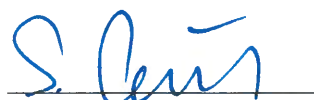
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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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
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Mannheim, 22 October 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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
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Produktname/Product name: **ISE Cleaning Solution / Elecsys SysClean**

Art.-Nr./Cat. No.: **11298500316**

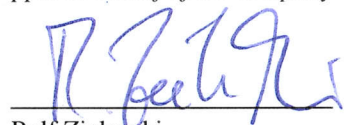
Beschreibung/Description: Zur Reinigung von ISE-Einheiten in Geräten von Roche/Hitachi.
Zur Reinigung von Elecsys und **cobas e** Immunoassay-Systemen.
For the cleaning of ISE units on Roche/Hitachi analyzers.
*For the cleaning of Elecsys and **cobas e** immunoassay analyzers.*

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

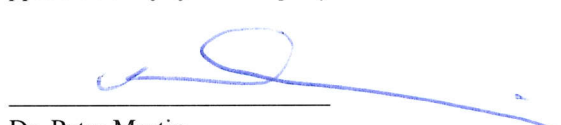
Roche Diagnostics GmbH

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

Kontaktadresse/Contact address: Roche Diagnostics GmbH
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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 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 Elektroden und zur Verwendung mit **cobas c** Systemen zur Reinigung des ISE-Fließwegs.

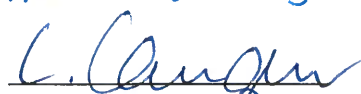
*ISE Deproteinizer is a cleaning solution intended for use with the COBAS INTEGRA and **cobas c 111** ISE modules for cleaning the ionselective electrodes and intended for use with **cobas c** systems for cleaning the ISE flow path.*

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

Kontaktadresse/Contact address: Roche Diagnostics GmbH
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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. Gabriele Nehl
Dr. M. Thein
Head of Quality & Regulatory
Management
Professional Diagnostics

i. V./on behalf of the company

A. Schenkel
A. Schenkel
Head of Quality Control
Professional Diagnostics

Kontaktadresse/Contact address: Roche Professional Diagnostics
Abt./Dept. Global Regulatory Affairs
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ISE Diluent Gen2.doc - la

Roche Diagnostics GmbH

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Sitz der Gesellschaft:
Mannheim
Registergericht Mannheim
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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D-68305 Mannheim

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

i.v. Gabriele Hehl
Dr. M. Thein
Head of Quality & Regulatory
Management
Professional Diagnostics

i. V./on behalf of the company

A. Schenkel
A. Schenkel
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ISE Internal Standard Gen2.doc - la

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

i. V./on behalf of the company

d.v. Gabriele Rebl

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

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ISE Reference Electrolyte.doc - la

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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.

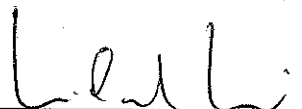
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Mannheim, 27.06.2006

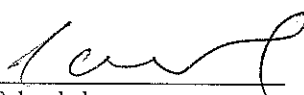
Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company



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



A. Schenkel
Head of Quality Assurance
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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.

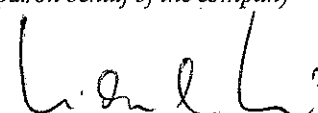
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils 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.

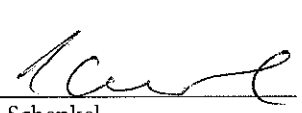
Mannheim, 27.06.2006

Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company


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


A. Schenkel
Head of Quality Assurance
Centralized Diagnostics

Kontaktadresse/Contact address: Roche Centralized Diagnostics
Abt./Dept. Regulatory Affairs
Sandhofer Straße 116
D-68305 Mannheim
Fax: +49 621/759 1448

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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.:

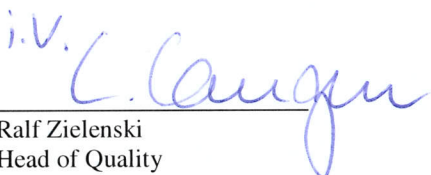
Y4300

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



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

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)

- ☒ 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

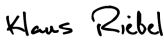
NB Ident. No.: 0123

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

Mannheim, 6 December 2024

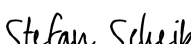
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

5E57330EEFE04C4...

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

ppa./on behalf of the company

DocuSigned by:

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

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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

☐ 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

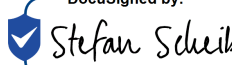
ppa./on behalf of the company

DocuSigned by:

485913ABEB04408...

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

ppa./on behalf of the company

DocuSigned by:

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

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

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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