

## EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)

*as per Annex IV of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)*

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: **Elecsys Anti-HBc II**

Art.-Nr./Cat. No.: **09014926190**

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung der IgG- und IgM-Antikörper gegen das Hepatitis B-Core-Antigen in Humanserum und -plasma.  
Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.

*Immunoassay for the in vitro qualitative determination of IgG and IgM antibodies to the hepatitis B core antigen in human serum and plasma.  
The electrochemiluminescence immunoassay "ECLIA" is intended for use on **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.

*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, 31 May 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

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

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

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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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: **Elecsys Anti-HBe**

Art.-Nr./Cat. No.: **07026838190**

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von humanen Antikörpern gegen Hepatitis B e Antigen (HBeAg) in Humanserum und – plasma.  
Der **ElektroChemiLumineszenz ImmunoAssay "ECLIA"** ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.  
*Immunoassay for the in vitro qualitative determination of human antibodies to the hepatitis B e antigen (HBeAg) in human serum and plasma.*  
*The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.*

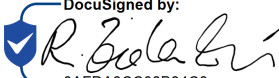
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

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Mannheim, 3 February 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

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

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

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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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: Elecsys Anti-HBs II

Art.-Nr./Cat. No.: 08498598190

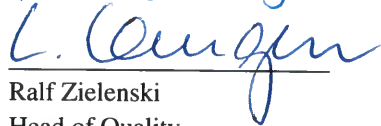
Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung von Humanantikörpern gegen das Hepatitis-B-Oberflächenantigen (HBsAg) in Humanserum und -plasma.  
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.  
*Immunoassay for the in vitro quantitative determination of human antibodies to the hepatitis B surface antigen (HBsAg) in human serum and plasma.*  
*The electrochemiluminescence immunoassay "ECLIA" is intended for use on **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, 3 September 2019

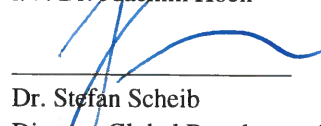
Roche Diagnostics GmbH

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  
i.V. Dr. Joachim Hoch



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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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: **Elecsys Anti-HCV II**

Art.-Nr./Cat. No.: **08836981190**  
**08837031190**  
**08837058190**

Beschreibung/Description: Der Elecsys Anti-HCV II Test ist ein diagnostischer In-vitro-Test für den qualitativen Nachweis von Antikörpern gegen Hepatitis-C-Virus (HCV) in Humanserum und -plasma.

Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.

*The Elecsys Anti-HCV II assay is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.*

*The electrochemiluminescence immunoassay "ECLIA" is intended for use on **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.

*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, 9 February 2022


Roche Diagnostics GmbH

ppa./on behalf of the company

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

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

Dr. Stefan Scheib  
Network Lead Core Lab, 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

## **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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys Anti-Tg	09004998190	7613336011419X
Elecsys Anti-Tg	09005021190	7613336011429Z
Anti-Tg CalSet	09005030190	761333601143A3

**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, 7 December 2021

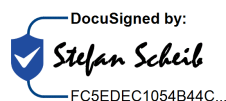
Roche Diagnostics GmbH

ppa./on behalf of the company

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

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

Dr. Stefan Scheib  
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*

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: **Anti-TPO CalSet**  
Art.-Nr./Id. No.: **06472931**  
Beschreibung/Description: Anti-TPO CalSet wird zur Kalibration des quantitativen Elecsys Anti-TPO Tests auf Elecsys und **cobas e** Immunoassay-Systemen verwendet.  
*Anti-TPO CalSet is used for calibrating the quantitative Elecsys Anti-TPO assay on the Elecsys and cobas e immunoassay 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, 19.09.2013

Roche Diagnostics GmbH  
ppa./on behalf of the company



Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics

i. V./on behalf of the company



Dr. C. Fleischer  
Head of Quality Control Penzberg  
Roche Diagnostics Global Operations

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

06472931\_Anti-TPO CalSet - la

**Roche Diagnostics GmbH**      Diagnostics Division

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

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher: Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan



## **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: **Elecsys Anti-TPO**

Art.-Nr./Cat. No.: **07026935190**

Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung von Thyreoperoxidase-Antikörper in Humanserum und -plasma. Die Anti-TPO-Bestimmung dient als Hilfsmittel zur Diagnose von autoimmunen Schilddrüsenerkrankungen.

Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.

*Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma. The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.*

*The electrochemiluminescence immunoassay "ECLIA" is intended for use on **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.

*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, 24 February 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

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

ppa./on behalf of the company

DocuSigned by:  
  
FC5EDEC1054B44C...

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

## **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:*** AssayTip/AssayCup tray

***Cat.-No.:*** 05694302001

***Basic UDI-DI:*** 761333601957BN

***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.*

Mannheim, 23 November 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

DocuSigned by:  
  
A7F0BA9FE91A46A...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
FC5EDEC1054B44C...

Dr. Stefan Scheib  
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

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
CleanCell M	04880293190	761333601330A4
CleanCell M	04880293214	761333602614AU

**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.

Mannheim, 30 May 2022


Roche Diagnostics GmbH

*ppa./on behalf of the company*

DocuSigned by:  
  
A7F0BA9FE91A46A...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
FC5EDEC1054B44C...

Dr. Stefan Scheib  
Network Lead Core Lab, 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

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as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116  
D-68305 Mannheim

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

Produktname/Product name: **Diluent Universal**

Art.-Nr./Cat. No.: **07299001190**

Beschreibung/Description: Diluent Universal dient als Verdünnungsmedium für Proben in  
Verbindung mit Elecsys Test-Reagenzien.  
*Diluent Universal is used as a sample diluent in conjunction with  
Elecsys assay reagents.*

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-Diagnostika 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, 02 June 2016

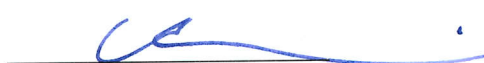
Roche Diagnostics GmbH

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  
D-68305 Mannheim