



## 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: Roche Professional Diagnostics  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

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: **Assay Tip/Assay Cup**

Art.-Nr./Id. No.: 12102137001

Beschreibung/Description: The Assay Tip/Assay Cup is used as an IVD-accessory on the following systems:  
E170 module  
cobas e 601 module  
cobas e 602 module

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, 04. Nov. 2013  
Roche Diagnostics GmbH  
ppa./on behalf of the company

Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics

ppa./on behalf of the company

Ralf Zielenski  
Head of Quality GPS and RDI  
Roche Diagnostics International Ltd

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

## **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:* CleanCell M  
*Cat.-No.:* 04880293190  
*Basic UDI-DI:* 761333601330A4  
*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, 24 August 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

## 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 Parliaments 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 HBsAg II

Art.-Nr./Cat. No.: 08814856190

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis B Oberflächen-Antigen (HBsAg) 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 hepatitis B surface antigen (HBsAg) in human serum and plasma.*

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

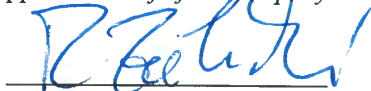
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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 October 2019

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

## 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 Parliaments 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: **PreciControl HBsAg II**

Art.-Nr./Cat. No.: **04687876190**

Beschreibung/Description: PreciControl HBsAg II dient zur Qualitätskontrolle der Elecsys HBsAg II und Elecsys HBsAg II Auto Confirm Immunoassays auf Elecsys und **cobas e** Immunoassay-Analyzern.

*PreciControl HBsAg II is used for quality control of the Elecsys HBsAg II and Elecsys HBsAg II Auto Confirm immunoassays on the Elecsys and **cobas e** immunoassay analyzers.*

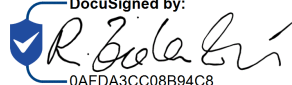
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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, 26 August 2020

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:  
  
0AFDA3CC08B94C8...

Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

ppa./on behalf of the company

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

## 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 Parliaments 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: **PreciControl Anti-HCV**

Art.-Nr./Cat. No.: **03290379190**

Beschreibung/Description: PreciControl Anti-HCV dient zur Qualitätskontrolle des Anti-HCV II Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.  
*PreciControl Anti-HCV is used for quality control of the Anti-HCV II immunoassay on the Elecsys and **cobas e** immunoassay analyzers.*

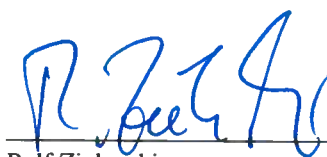
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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, 29 June 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

i.V. Dr. Manfred Böhm



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

## 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 Parliaments 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 HIV combi PT**

Art.-Nr./Cat. No.: **08924163190**  
**08924180190**

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von HIV-1 p24-Antigenen und Antikörper gegen HIV-1, einschließlich Gruppe O, und HIV-2 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 HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma.*

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

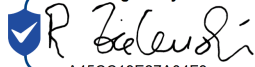
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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, 29 May 2020

Roche Diagnostics GmbH

*ppa./on behalf of the company*

DocuSigned by:  
  
A45CC19E27A04F3...

---

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



## 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 Parliaments 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: **PreciControl HIV Gen II**

Art.-Nr./Cat. No.: **06924107190**

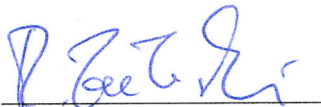
Beschreibung/Description: PreciControl HIV Gen II dient zur Qualitätskontrolle von Elecsys HIV combi PT, Elecsys HIV Duo und Elecsys HIV Ag Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.  
*PreciControl HIV Gen II is used for quality control of the Elecsys HIV combi PT, Elecsys HIV Duo and Elecsys HIV Ag immunoassays on the 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.  
*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 March 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  
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:* PreClean M  
*Cat.-No.:* 03004899190  
*Basic UDI-DI:* 761333601258AM  
*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, 24 August 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*

*Product name:* ProbeWash M  
*Cat.-No.:* 03005712190  
*Basic UDI-DI:* 761333601259AP  
*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, 24 August 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*

*Product name:* ProCell M  
*Cat.-No.:* 04880340190  
*Basic UDI-DI:* 761333601332A8  
*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, 24 August 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

## 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: **PreciControl Syphilis**  
Art.-Nr./Id. No.: **06923364**  
Beschreibung/Description: PreciControl Syphilis dient zur Qualitätskontrolle des Elecsys Syphilis Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.  
*PreciControl Syphilis is used for quality control of the Elecsys Syphilis immunoassay 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, 03.02.2014

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

06923364\_PreciControl Syphilis - 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: Dr. Ursula Redeker, Sprecherin;  
Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan