# 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<br>Sandhofer Straße 116<br>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*: | **IgE CalSet** |
| Art.-Nr./*Id. No.*: | **11930427** |
| Beschreibung/*Description*: | IgE CalSet wird zur Kalibration des quantitativen Elecsys IgE II Tests auf Elecsys und **cobas e** Immunoassay-Systemen verwendet.<br>*IgE CalSet is used for calibrating the quantitative Elecsys IgE II 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, 02.07.2013
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

Digitally signed by Lazari Cristina
Date: 2021.11.15 14:36:58 EET
Reason: MoldSign Signature
Location: Moldova

11930427_IgE CalSet - la

# 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<br>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 IgE II** |
| Art.-Nr./*Cat. No.*: | **07027516190** |
| Beschreibung/*Description*: | Immunologischer In-vitro-Test zur quantitativen Bestimmung von Immunglobulin E in Humanserum und -plasma.<br>Die Bestimmung von Gesamt-IgE ist ein nützliches Hilfsmittel bei der Diagnose von allergischen Erkrankungen.<br>Der **E**lektro**C**hemi**L**umineszenz **I**mmuno**A**ssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.<br><br>*Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma.*<br>*Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.*<br>*The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "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, 3 February 2021

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:
Dr. Stefan Scheib
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



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

# *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<br>68305 Mannheim<br>Germany |
| *Single Registration Number:* | *TBD (application filed; confirmation pending)* |
| *Authorized Representative:* | N/A |
| *Address:* | |
| *Single Registration Number:* | N/A |

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

| **Product Name** | **Cat. No.** | **Basic UDI-DI** |
|---|---|---|
| Elecsys Insulin | 07027559190 | 761333600615AG |
| Elecsys Insulin | 12017547122 | 761333600744AU |
| Insulin CalSet | 12017504122 | 761333600743AS |

*Risk Class:* ☐ *A* ☒ *B* ☐ *C* ☐ *D*

*Conformity Route:*
☐ *Self-Declaration of Conformity (Class A)*
☒ *Technical Documentation Assessment Class B/C – Annex IX*
☐ *Technical Documentation Assessment Class D – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX*
☐ *Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX*

*Certificates:*
☒ *EU QM Certificate No.:* V12 010283 0639
☐ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):*

*Other:* ☐ *Common Specifications:*

| | |
|---|---|
| *Notified Body (NB) Name:* | *TÜV Süd Product Service GmbH* |
| *NB Address:* | *Ridlerstraße 65*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



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

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

Mannheim, 30 March 2021

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:
Stefan Scheib
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:* | Roche Professional Diagnostics<br>Sandhofer Straße 116<br>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 Anti-HBc IgM** |
| Art.-Nr./*Id. No.*: | 11876333 |
| Beschreibung/*Description*: | PreciControl Anti-HBc IgM dient zur Qualitätskontrolle des Elecsys Anti-HBc IgM Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.<br>*PreciControl Anti-HBc IgM is used for quality control of the Elecsys Anti-HBc IgM 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, 21.08.2013

Roche Diagnostics GmbH

| | |
|---|---|
| ppa./*on behalf of the company* | i. V./*on behalf of the company* |
| Dr. M. Thein<br>Head of Quality<br>Roche Professional Diagnostics | Dr. C. Fleischer<br>Head of Quality Control Penzberg<br>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



**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

# 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<br>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-HBc II** |
| Art.-Nr./*Cat. No.*: | **04927931190** |
| Beschreibung/*Description*: | PreciControl Anti-HBc II dient zur Qualitätskontrolle des Elecsys Anti-HBc II Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.<br>*PreciControl Anti-HBc II is used for quality control of the Elecsys Anti-HBc II 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-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, 18 May 2016

Roche Diagnostics GmbH

ppa./*on behalf of the company*
i.V. C. Quergan
Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*
i.A. d. M.
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



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

# 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:* | Roche Professional Diagnostics<br>Sandhofer Straße 116<br>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 Anti-HBe** |
| Art.-Nr./*Id. No.*: | **11876384** |
| Beschreibung/*Description*: | PreciControl Anti-HBe dient zur Qualitätskontrolle des Elecsys Anti-HBe Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.<br>*PreciControl Anti-HBe is used for quality control of the Elecsys Anti-HBe 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, 27.08.2012

Roche Diagnostics GmbH
ppa./*on behalf of the company* i. V./*on behalf of the company*

| | |
|---|---|
| Dr. M. Thein | Dr. B. Rauschel |
| Head of Quality | Head of Quality Control Penzberg |
| Roche Professional Diagnostics | 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



**Roche Diagnostics GmbH** Diagnostics Division

Roche Diagnostics GmbH; Werk Mannheim; Sandhofer Str. 116; D 63805 Mannheim; Telefon +49 621-759-0; Telefax +49 621 759 2890

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 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:* | Roche Professional Diagnostics<br>Sandhofer Straße 116<br>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 Anti-HBs** |
| Art.-Nr./*Id. No.*: | **11876317** |
| Beschreibung/*Description*: | PreciControl Anti-HBs dient zur Qualitätskontrolle des Elecsys Anti-HBs Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.<br>*PreciControl Anti-HBs is used for quality control of the Elecsys Anti-HBs 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, 18.09.2012

Roche Diagnostics GmbH

| | |
|---|---|
| ppa./*on behalf of the company* | i. V./*on behalf of the company* |
| Dr. M. Thein<br>Head of Quality<br>Roche Professional Diagnostics | Dr. B. Rauschel<br>Head of Quality Control Penzberg<br>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

11876317_PreciControl Anti-HBs - la

Product Service

Add value.
Inspire trust.

# Verification Report

according to Directive 98/79/EC Annex IV.6

**No.** ROC-03290379 21 09 056313

**Manufacturer:** **ROCHE Diagnostics GmbH**
Sandhofer Strasse 116
D-68305 Mannheim

**Product:** **PreciControl Anti-HCV**
**Elecsys and cobas e analyzers**

Mat-Nr.: 03290379190
Anti-HCV PC Elecsys
Batch: 54174402
2 - 8 °C
Lot: 040000755498 13.09.2021
Sample No./Type:200442123/Y2

**Batch:** **54174402**

**Expiry Date:** **31.08.2022**

The above mentioned batch meets the batch release criteria established during design examination and may be placed on the market. The design examination certificate issued for this product is V7 010283 0630 Rev.01.

**Date,** 2021-09-20

A. Ait Benarrou

Adobe Sign Transaction Number: CBJCHBCAABAAW0sbw3g6kGNKX2OnvZSNe1kGx8dGL2yV

i.A. Ahmed Ait Benarrou
In-vitro Diagnostics

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 98/79/EC concerning In-vitro Diagnostic Medical Devices with Identification No. 0123.

**To:**
ROCHE Diagnostics GmbH
Dr. Rainer Bäuerlein
08856 / 60-3647

# 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:* | Roche Professional Diagnostics<br>Sandhofer Straße 116<br>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 HBeAg** |
| Art.-Nr./*Id. No.*: | **11876376** |
| Beschreibung/*Description*: | PreciControl HBeAg dient zur Qualitätskontrolle des Elecsys HBeAg Immunoassays an Elecsys und **cobas e** Immunoassay-Systemen.<br>*PreciControl HBeAg is used for quality control of the Elecsys HBeAg 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.
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Mannheim, 20.08.2012

Roche Diagnostics GmbH
ppa./*on behalf of the company* i. V./*on behalf of the company*

| | |
|---|---|
| Dr. M. Thein | Dr. B. Rauschel |
| Head of Quality | Head of Quality Control Penzberg |
| Roche Professional Diagnostics | 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



**Roche Diagnostics GmbH** Diagnostics Division
Roche Diagnostics GmbH; Werk Mannheim; Sandhofer Str. 116; D 63805 Mannheim; Telefon +49 621-759-0; Telefax +49 621 759 2890

# EG-Konformitätserklärung/*EC Declaration of Conformity*

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| | |
|---|---|
| Hersteller/*Manufacturer*: | Roche Diagnostics GmbH |
| Adresse/*Address:* | Sandhofer Strasse 116<br>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.<br><br>*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:
Stefan Scheib
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



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: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker