

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 |
|-----------------|-------------|----------------|
| Elecsys Insulin | 12017547122 | 761333600744AU |
| Elecsys Insulin | 12017547214 | 761333602084AK |

Intended Use:

Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia.

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

| Product Name | Cat. No. | Basic UDI-DI |
|-----------------|-------------|----------------|
| Elecsys Insulin | 07027559190 | 761333600615AG |
| Elecsys Insulin | 07027559214 | 761333602058AJ |

Intended Use:

Immunoassay for the in vitro quantitative determination of human insulin in human serum and plasma. The determination of insulin is utilized in the diagnosis and therapy of various disorders of carbohydrate metabolism, including diabetes mellitus and hypoglycemia.

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

| Product Name | Cat. No. | Basic UDI-DI |
|----------------|-------------|----------------|
| Insulin CalSet | 12017504122 | 761333600743AS |

Intended Use:

Insulin CalSet is used for calibrating the quantitative Elecsys Insulin assay on cobas e immunoassay analyzers.

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, 30 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:
Stefan Scheib
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Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

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

| Product Name | Cat. No. | Basic UDI-DI |
|---------------------|-----------------|---------------------|
| PreClean II M | 06908853190 | 761333601449AW |
| PreClean II M | 06908853214 | 761333602615AW |

Intended Use:

Wash solution for the removal of substances which potentially interfere with the detection of signals. PreClean II M is used on cobas e immunoassay analyzers in conjunction with Elecsys assay reagents. PreClean II M can be used with all reagent lots.

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

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Mannheim, 16 June 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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Christina Schmid
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Dr. Christina Schmid
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| Product Name | Cat. No. | Basic UDI-DI |
|---------------------|-----------------|---------------------|
| ProCell II M | 06908799190 | 761333601448AU |
| ProCell II M | 06908799214 | 761333602616AY |

Intended Use:

System solution for generating electrochemical signals in cobas e immunoassay analyzers.
 ProCell II M is used in conjunction with Elecsys assay reagents.
 ProCell II M can be used with all reagent lots.

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
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| Product Name | Cat. No. | Basic UDI-DI |
|----------------------|-------------|----------------|
| Elecsys Prolactin II | 03203093190 | 761333600587B4 |
| Elecsys Prolactin II | 03203093214 | 761333600588B6 |
| Elecsys Prolactin II | 07027737190 | 761333600617AL |
| Elecsys Prolactin II | 07027737214 | 761333602061A7 |
| Elecsys Prolactin II | 09755764190 | 761333602984BY |

Intended Use:

Immunoassay for the in vitro quantitative determination of prolactin in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|---------------------|-------------|----------------|
| Prolactin II CalSet | 03277356190 | 761333600591AT |

Intended Use:

Prolactin II CalSet is used for calibrating the quantitative Elecsys Prolactin II assay on cobas e immunoassay analyzers.

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

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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

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

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Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

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| Product Name | Cat. No. | Basic UDI-DI |
|-------------------------|-------------|----------------|
| Elecsys Testosterone II | 08946353190 | 761333601076AD |
| Elecsys Testosterone II | 08946370190 | 7613336011319U |
| Elecsys Testosterone II | 09745963190 | 761333602858BS |

Intended Use:

Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

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
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 Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

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Other: Common Specifications:

Notified Body (NB) Name: TÜV Süd Product Service GmbH

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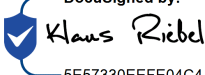
NB Ident. No.: 0123

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Mannheim, 7 August 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

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Dr. Klaus Riebel
Site Quality Head / Network Lead Penzberg

ppa./on behalf of the company

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Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

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| Product Name | Cat. No. | Basic UDI-DI |
|-------------------|-------------|----------------|
| Elecsys total PSA | 08791686190 | 761333600805AP |
| Elecsys total PSA | 08791732190 | 761333600807AT |
| Elecsys total PSA | 08791732214 | 761333602067AK |
| Elecsys total PSA | 09744860190 | 761333602871BJ |

Intended Use:

This assay, a quantitative in vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma, is indicated for the measurement of total PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for diagnosis of prostate cancer. The test is further indicated for serial measurement of tPSA to aid in the management of cancer patients.

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

| Product Name | Cat. No. | Basic UDI-DI |
|-------------------|-------------|----------------|
| Elecsys total PSA | 08791716190 | 761333600806AR |

Intended Use:

This assay, a quantitative in vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma, is indicated for the measurement of total PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for diagnosis of prostate cancer. The test is further indicated for serial measurement of tPSA to aid in the management of cancer patients.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e 601 and cobas e 602 immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|------------------|-------------|----------------|
| total PSA CalSet | 08838534190 | 761333600810AG |

Intended Use:

total PSA CalSet II is used for calibrating the quantitative Elecsys total PSA assay on cobas e immunoassay analyzers.

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*
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Other: *Common Specifications:*

Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
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NB Ident. No.: 0123

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Mannheim, 29 September 2023

Roche Diagnostics GmbH

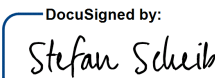
i.V./on behalf of the company

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Head of Pre-Market Quality Point of Care

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Global Head of Regulatory Affairs, Core Lab

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| Product Name | Cat. No. | Basic UDI-DI |
|--------------|-------------|----------------|
| Elecsys TSH | 08443432190 | 7613336001139K |
| Elecsys TSH | 08443432214 | 761333602065AF |
| Elecsys TSH | 08429324190 | 7613336001129H |

Intended Use:

Immunoassay for the in vitro quantitative determination of thyrotropin in human serum and plasma.
 The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|--------------|-------------|----------------|
| TSH CalSet | 08443459190 | 7613336001149M |

Intended Use:

TSH CalSet is used for calibrating the quantitative Elecsys TSH assay on cobas e immunoassay analyzers.

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:

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- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: Common Specifications:

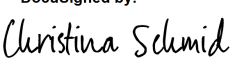
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
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NB Ident. No.: 0123

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

Mannheim, 7 December 2022

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

59311CC1CDA8480...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

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Global Head of Regulatory Affairs, Core Lab

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| Product Name | Cat. No. | Basic UDI-DI |
|------------------------|-------------|----------------|
| Elecsys Vitamin B12 II | 07212771190 | 761333600436AE |
| Elecsys Vitamin B12 II | 07028121190 | 7613336004029V |
| Elecsys Vitamin B12 II | 07028121214 | 761333602062A9 |
| Elecsys Vitamin B12 II | 09755896190 | 761333602982BU |

Intended Use:

Binding assay for the in vitro quantitative determination of vitamin B12 in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|-----------------------|-------------|----------------|
| Vitamin B12 II CalSet | 07212780190 | 761333600437AG |

Intended Use:

Vitamin B12 II CalSet is used for calibrating the quantitative Elecsys Vitamin B12 II assay on cobas e immunoassay analyzers.

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

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

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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

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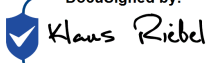
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Mannheim, 7 August 2024

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Dr. Klaus Riebel
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| Product Name | Cat. No. | Basic UDI-DI |
|-----------------------------|-------------|----------------|
| Elecsys Vitamin D total III | 09038078190 | 761333601067AC |
| Elecsys Vitamin D total III | 09038086190 | 761333601068AE |

Intended Use:

Binding assay for the in vitro quantitative determination of total 25-hydroxyvitamin D in human serum and plasma. This assay is to be used as an aid in the assessment of vitamin D sufficiency.

The electrochemiluminescence binding assay is intended for use on cobas e immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|----------------------------------|-------------|----------------|
| PreciControl Vitamin D total III | 09038124190 | 7613336010709Z |
| PreciControl Vitamin D total III | 09038124922 | 761333601071A3 |

Intended Use:

PreciControl Vitamin D total III is used for quality control of the Elecsys Vitamin D total III immunoassay on cobas e immunoassay analyzers.

| Product Name | Cat. No. | Basic UDI-DI |
|----------------------------|-------------|----------------|
| CalSet Vitamin D total III | 09038116190 | 761333601069AG |

Intended Use:

CalSet Vitamin D total III is used for calibrating the quantitative Elecsys Vitamin D total III assay on cobas e immunoassay analyzers.

Risk Class: A B C D

Conformity Route:

- Self-Declaration of Conformity (Class A)
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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:
NB Address:*

*TÜV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
0123*

NB Ident. No.:

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

Mannheim, 10 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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