

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 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)
- ☐ 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:
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

DocuSigned by:
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Dr. Christina Schmid
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ppa./on behalf of the company

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