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
Elecsys Vitamin D total III	09038086214	761333602941BE
Elecsys Vitamin D total III	09652060190	761333602738BF

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
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.

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.

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)

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; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

☒ 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, 18 August 2025

i.V./*on behalf of the company*

DocuSigned by:
Klaus Riebel
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Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

Mannheim, 15 August 2025

i.V./*on behalf of the company*

DocuSigned by:
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Stefan Grigarczik
Subchapter Lead Global Regulatory Affairs

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