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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 Everolimus	06633188190	7613336002169W

Intended Use:
Immunoassay for the in vitro quantitative determination of everolimus in human whole blood. The assay is used as an aid in the management of kidney, liver and heart transplant patients receiving everolimus therapy.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Everolimus	07027257190	761333600253A4

Immunoassay for the in vitro quantitative determination of everolimus in human whole blood. The assay is used as an aid in the management of kidney, liver and heart transplant patients receiving everolimus therapy.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
PreciControl Everolimus	07294131190	761333600444AD

Intended Use:
PreciControl Everolimus is used for quality control of the Elecsys Everolimus immunoassay on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Everolimus CalSet	06633196190	7613336002179Y

Intended Use:
Everolimus CalSet is used for calibrating the quantitative Elecsys Everolimus assay on cobas e immunoassay analyzers.

Digitally signed by Lazari Cristina
Date: 2024.10.15 11:58:39 EEST
Reason: MoldSign Signature
Location: Moldova

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

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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*
NB Ident. No.:	*0123*

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

Mannheim, 15 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

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