

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 Ferritin	03737551190	761333600602A7
Elecsys Ferritin	03737551214	761333602045A9
Elecsys Ferritin	04491785190	761333600609AM
Elecsys Ferritin	07027273190	761333600802AH
Elecsys Ferritin	07027273214	761333602055AC
Elecsys Ferritin	09755667190	761333602869BX

Intended Use:

Immunoassay for the in vitro quantitative determination of ferritin 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
Ferritin CalSet	03737586190	761333600603A9

Intended Use:

Ferritin CalSet is used for calibrating the quantitative Elecsys Ferritin 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

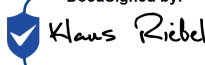
NB Ident. No.: 0123

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

Mannheim, 7 August 2024

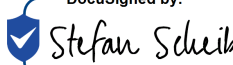
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

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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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