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. / REF	Basic UDI-DI
Elecsys Phospho-Tau (181P) CSF	08846693190	761333601180A9
Elecsys Phospho-Tau (181P) CSF	08846715190	761333601181AB

Intended Use:

The Elecsys Phospho-Tau (181P) CSF assay is an in vitro diagnostic immunoassay intended for the quantitative determination of the phosphorylated Tau protein in human CSF.
1. The Elecsys Phospho-Tau (181P) CSF assay is intended to be used alone or in combination with Elecsys β-Amyloid (1-42) CSF II assay as a ratio in adult subjects with mild cognitive impairment (MCI) as an aid to identify subjects who are at lower vs. higher risk of cognitive decline as defined by change in a clinical score within a 2 year period.
2. The Elecsys Phospho-Tau (181P) CSF assay is intended to be used in combination with Elecsys β-Amyloid (1-42) CSF II assay as a ratio in adult subjects with cognitive impairment being evaluated for AD and other causes of cognitive impairment wherein a positive and negative CSF result is concordant with positive and negative amyloid Positron Emission Tomography (PET) scan result, respectively.
3. The Elecsys Phospho-Tau (181P) CSF assay is intended to be used in combination with the Elecsys β-Amyloid (1-42) CSF II assay as a ratio in adult subjects with cognitive impairment being evaluated for AD and other causes of cognitive impairment. A negative result, defined as pTau/Abeta42 ratio value below cutoff, is consistent with a negative tau result based on the tau PET scan. A positive result, defined as pTau/Abeta42 ratio value above cutoff, is consistent with a positive tau result based on the tau PET scan.

Limitations of use
• The Elecsys Phospho-Tau (181P) CSF assay is an adjunct to other clinical diagnostic evaluations.
• A positive Elecsys Phospho-Tau (181P) CSF assay result and/or a positive Elecsys Phospho-Tau (181P) CSF to Elecsys β-Amyloid (1-42) CSF II ratio result does not establish a diagnosis of AD or other cognitive disorder.
• The safety and effectiveness of the Elecsys Phospho-Tau (181P) CSF assay have not been established for monitoring responses to therapies.

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 ☐ 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.: V13 010283 0732 ☐ 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 February 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Nicole Zein

Dr. Nicole Zein
Site Quality Head / Network Lead, Mannheim

Mannheim, 17. Februar 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Stefan Scheib

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

Contact address:

Roche Diagnostics GmbH
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