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 Total-Tau CSF	07356994190	761333600447AK

Intended Use:
The Elecsys Total-Tau CSF assay is an in vitro diagnostic immunoassay intended for the quantitative determination of the total Tau protein in human CSF.
1. The Elecsys Total-Tau CSF assay is intended to be used alone or in combination with Elecsys β-Amyloid (1-42) CSF 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 Total-Tau CSF assay is intended to be used in combination with Elecsys β-Amyloid (1-42) CSF 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.
Limitations of use
- The Elecsys Total-Tau CSF assay is an adjunct to other clinical diagnostic evaluations.
- A positive Elecsys Total-Tau CSF assay result and/or a positive Elecsys Total-Tau CSF to Elecsys β-Amyloid (1-42) CSF ratio result does not establish a diagnosis of AD or other cognitive disorder.
- The safety and effectiveness of the Elecsys Total-Tau CSF assay have not been established for monitoring responses to therapies.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Risk Class: ☐ *A* ☒ *B* ☐ *C* ☐ *D*

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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):* ☐ *Common Specifications:*
Other:	
Notified Body (NB) Name: *NB Address:* *NB Ident. No.:*	*TÜV Süd Product Service GmbH* *Ridlerstraße 65* *80339 Munich* *Germany* *0123*

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

Mannheim, 14 March 2023

Roche Diagnostics GmbH

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

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