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 β-Amyloid (1-42) CSF II	08821909190	761333601174AE
Elecsys β-Amyloid (1-42) CSF II	08821941190	761333601175AG

Intended Use:

Elecsys β-Amyloid (1-42) CSF II is an in vitro diagnostic immunoassay intended for the quantitative determination of the β-amyloid (1-42) protein concentration in human cerebrospinal fluid (CSF).

1. The Elecsys β-Amyloid (1-42) CSF II assay is intended to be used in adult subjects with cognitive impairment being evaluated for Alzheimer disease (AD) and other causes of cognitive impairment. Result above the cutoff is consistent with a negative amyloid positron emission tomography (PET) scan. Negative β-amyloid PET scans indicate sparse to no neuritic plaques and are inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD.
2. The Elecsys β-Amyloid (1-42) CSF II assay is intended to be used in combination with Elecsys Phospho-Tau (181P) CSF or Elecsys Total-Tau 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 are concordant with positive and negative amyloid Positron Emission Tomography (PET) scan result, respectively.
3. Elecsys β-Amyloid (1-42) CSF II assay is intended to be used alone or in combination with Elecsys Phospho-Tau (181P) CSF or Elecsys Total-Tau 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.

Limitations of use

- Elecsys β-Amyloid (1-42) CSF II assay is an adjunct to other clinical diagnostic evaluations.
- A positive Elecsys β-Amyloid (1-42) CSF II assay result and/or a positive Elecsys Phospho-Tau (181P) CSF or Elecsys Total-Tau 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 β-Amyloid (1-42) CSF II assay have not been established for monitoring responses to therapies.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
PreciControl β-Amyloid (1-42) II	08821968190	761333601177AL

Intended Use:
PreciControl β-Amyloid (1-42) II is used for quality control of the Elecsys β-Amyloid (1-42) CSF II immunoassay on cobas e immunoassayanalyzers.

Product Name	Cat. No.	Basic UDI-DI
CalSet β-Amyloid (1-42) II	08821976190	761333601176AJ

Intended Use:
CalSet β-Amyloid (1-42) II is used for calibrating the quantitative Elecsys β-Amyloid (1-42) CSF II 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, 30 March 2023

Roche Diagnostics GmbH

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

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