

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 S100	08817278190	7613336010139M
Elecsys S100	08817324190	7613336010149P

Intended Use:

Immunoassay for the in vitro quantitative determination of S100 (S100 A1B and S100 BB) in human serum.
 This assay can be used

- to aid in the management of patients suffering from malignant melanoma (Elecsys S100 assay is not suitable for the diagnosis of malignant melanoma)
- to aid in the management of patients after potential brain injury in conjunction with clinical information and imaging techniques

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

Product Name	Cat. No.	Basic UDI-DI
S100 CalSet	03289834190	761333600934B3

Intended Use:

S100 CalSet is used for calibrating the quantitative Elecsys S100 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

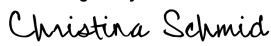
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 30 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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Dr. Christina Schmid

Head of Pre-Market Quality Core Lab

DocuSigned by:

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Dr. Stefan Scheib

Global Head of Regulatory Affairs, Core Lab

Contact address:

Roche Diagnostics GmbH

Abt./Dept. Global Regulatory Affairs

Sandhofer Strasse 116

D-68305 Mannheim