

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 PSA	08791686190	761333600805AP
Elecsys total PSA	08791716190	761333600806AR
Elecsys total PSA	08791732190	761333600807AT
total PSA CalSet II	08838534190	761333600810AG

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:

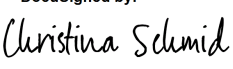
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 17 October 2022

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

59311CC1CDA8480...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

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



Document Information:

Document Author:	Deichfuss, Beate {DQRD~Mannheim}
Business Area / Unit:	Roche Professional Diagnostics
Confidentiality:	Confidential
Document Class:	Quality System Record
Document Type:	Quality System Record
Document Creator:	Deichfuss, Beate {DQRD~Mannheim}
Document Lifecycle Status:	Signed
Valid From:	24-Oct-2022 08:16:26 (UTC)
Valid To:	
Document Title:	R_Conf_Elecsys_tPSA_and_CalSet II
Document Number:	0000000000001200000613496
Document Version:	02
Template:	No
Global Group:	Regulatory Affairs
Global SubGroup:	CE Conformity Reagent
Language:	English
Site:	RDG Germany
Department:	R_RegAffairs RPD Germany
Document Applies To:	R_RegAffairs RPD Germany
Document Description:	Elecsys total PSA, total PSA CalSet II (IVDR)

Electronic Signatures:

Signed By:	deichfub (Beate Deichfuss {DQRDB})
Role:	Approver
Signature Differentiation:	Regulatory Affairs
Signed Date:	24-Oct-2022 08:09:58 (UTC)

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total PSA CalSet II	08838534190	761333600810AG

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:

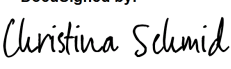
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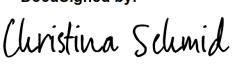
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