EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer:
Address:

Roche Diagnostics GmbH
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*

Digitally signed by Lazari Cristina
Date: 2022.11.01 11:34:19 EET
Reason: MoldSign Signature
Location: Moldova

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

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:
Christina Schmid
59311CC1CDA8480...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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
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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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☐ *Technical Documentation Assessment Class D – Annex IX*
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