

## 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:  
*Christina Schmid*  
59311CC1CDA8480...

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

*ppa./on behalf of the company*

DocuSigned by:  
*Stefan Scheib*  
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Dr. Stefan Scheib  
Global Head of Regulatory Affairs, Core Lab

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Roche Diagnostics GmbH  
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## 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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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:

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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  
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