

EC 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: TBD (application filed; confirmation pending)

Authorized Representative: N/A
Address:

Single Registration Number: N/A

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Elecsys Anti-TPO	06368590190	761333600969BN
Anti-TPO CalSet	06472931190	761333600977BM
Elecsys Anti-TPO	07026935190	761333600988BS

Risk Class: A B C D

Conformity Route:

- Self-Declaration of Conformity (Class A)
- 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 May 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:

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Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

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Product Name	Cat. No.	Basic UDI-DI
Elecsys TSH	08429324190	7613336001129H
Elecsys TSH	08443432190	7613336001139K
TSH CalSet	08443459190	7613336001149M

Risk Class: A B C D

Conformity Route:

- Self-Declaration of Conformity (Class A)
- Technical Documentation Assessment Class B/C – Annex IX
- Technical Documentation Assessment Class D – Annex IX
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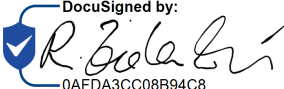
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 5 February 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

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DocuSigned by:

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