

## **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 Tacrolimus | 05889057190 | 761333600372AD |
| Elecsys Tacrolimus | 07251254190 | 761333600441A7 |
| Tacrolimus CalSet  | 05889065190 | 761333600373AF |

**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:

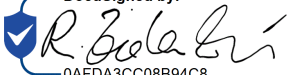
**Notified Body (NB) Name:** TÜV Süd Product Service GmbH  
**NB Address:** Ridlerstraße 65  
 80339 Munich  
 Germany  
**NB Ident. No.:** 0123

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

Mannheim, 15 February 2021

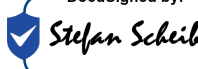
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

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Dr. Stefan Scheib  
Director Global Regulatory Affairs  
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