

## **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:** DE-MF-000006260

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

**Product name:** **Activator**  
**Cat.-No.:** **04663632190**  
**Basic UDI-DI:** **761333601299B3**  
**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.:*  
 *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):*

**Other:**  *Common Specifications:*

**Notified Body (NB) Name:** N/A  
**NB Address:**

**NB Ident. No.:** N/A

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

Mannheim, 9 September 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

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Ralf Zielenski  
Head Q&R Compliance, PRRC RDG  
Centralised and Point of Care Solutions

*i.V./on behalf of the company*

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Dr. Joachim Hoch  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

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