

## **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*

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
SMS	04489225190	761333601270AB
SMS	05172136190	761333601355AL
SMS	05172136214	761333601356AN
SMS	08063478190	761333601535AQ

**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, 26 August 2021

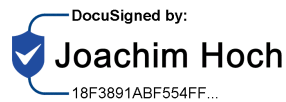
Roche Diagnostics GmbH

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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