

## **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:*** AssayTip/AssayCup tray

***Cat.-No.:*** 05694302001

***Basic UDI-DI:*** 761333601957BN

***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, 23 November 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

*ppa./on behalf of the company*

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

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