

## **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:*** **Sample Cup Micro 13/16**

***Cat.-No.:*** **05085713001**

***Basic UDI-DI:*** **761333601955BJ**

***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.*

and

- fulfills the requirements of DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Mannheim, 21 January 2022

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  
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