

**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:* PreClean II M  
*Cat.-No.:* 06908853190  
*Basic UDI-DI:* 761333601449AW  
*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, 24 August 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

DocuSigned by:  
A handwritten signature of Ralf Zielenski in black ink, positioned over a horizontal line.  
A7F0BA9FE91A46A...

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

*ppa./on behalf of the company*

DocuSigned by:  
A handwritten signature of Stefan Scheib in black ink, positioned over a horizontal line.  
FC5EDEC1054B44C...

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

*Contact address:*

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