

## **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>
PreciControl Varia	05618860190	761333600961B6
PreciControl Varia	05618860922	761333600962B8

**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.: V12 010283 0639
- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

**Other:**  Common Specifications:

**Notified Body (NB) Name:** TÜV Süd Product Service GmbH  
**NB Address:** Ridlerstraße 65  
 80339 Munich  
 Germany  
**NB Ident. No.:** 0123

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

Mannheim, 18 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

DocuSigned by:  
  
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Dr. Stefan Scheib  
Director Global Regulatory Affairs  
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