

## **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>
ISE Internal Standard Gen.2	04522320190	761333600651AL
ISE Internal Standard Gen.2	04880455190	761333600663AT
ISE Reference Electrolyte	10820652216	761333600706AL
ISE Reference Electrolyte	11360981216	761333600718AT
ISE Reference Electrolyte	08392013190	761333600687B9
ISE Standard High	11183982216	761333600711AD
ISE Standard Low	11183974216	761333600709AS

**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, 5 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

i.V./on behalf of the company

DocuSigned by:  
  
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Dr. Joachim Hoch  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

*Contact address:*

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