

## **EU 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	Cat. No.	Basic UDI-DI
Roche CARDIAC POC Troponin T	07007302190	761333601455AR
Roche CARDIAC POC Troponin T	07007302191	7613336020229V

### ***Intended Use:***

Quantitative immunological test for the detection of cardiac troponin T in heparinized venous blood for use with the cobas h 232 instrument. The test is intended as an early aid in diagnosis of acute myocardial infarction and identification of patients with an elevated mortality risk. The Roche CARDIAC POC Troponin T Test is intended for near-patient testing.

Not for self-testing.

**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.: V10 010283 0641
- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0648

**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, 28 February 2023

Roche Diagnostics GmbH

*i.V./on behalf of the company*

DocuSigned by:  
*Bernd Röttinger*  
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Dr. Bernd Röttinger  
Head of Pre-Market Quality Point of Care

*ppa./on behalf of the company*

DocuSigned by:  
*Stefan Scheib*  
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Dr. Stefan Scheib  
Global Head of Regulatory Affairs, Core Lab

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