EC Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer: *Address:*	Roche Diagnostics GmbH 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:	**Roche CARDIAC IQC**
Cat.-No.:	**04880668190**
Basic UDI-DI:	**761333601334AC**
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: *NB Address:*	*N/A*
NB Ident. No.:	*N/A*

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

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Mannheim, 11 March 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

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