QUIDEL

DECLARATION OF CONFORMITY

DoC#: TF-1001, Rev L

Legal Manufacturer: Quidel Cardiovascular Inc.
Legal Manufacturer's Address: 9975 Summers Ridge Road
San Diego, CA 92121 USA

Declares that the product
Product Name and Model(s):

REF 97400EU	Quidel Triage® Cardio3 Panel
REF 97500EU	Quidel Triage® Cardio2 Panel
REF 98600EU	Quidel Triage® Troponin I Test
REF 98832EU	Quidel Triage® Troponin I Test
REF 88733	Quidel Triage® Total 3 Control 1
REF 88734	Quidel Triage® Total 3 Control 2

As described above are in conformity with the requirements of the standards listed in Appendix 1, Applicable Standards and Guidelines.

Additional Information:

EC Representative's Name: Medical Device Safety Service GmbH
EC Representative's Address: Schiffgraben 41
30175 Hannover
Germany

Management System: GQM, Quality Manual, Revision O

Quality System Certificate No: QS2 040885 0029, Expires December 20, 2024

Conformity Pathway: Annex III

Classification: Article 9, Section 1, Other IVD

This Declaration of Conformity is issued under the sole responsibility of Quidel Cardiovascular Inc. I, the undersigned, hereby declare on behalf of the manufacturer Quidel Cardiovascular Inc. that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Rachael S. Williamson
Associate Director, Regulatory Affairs

San Diego, California, USA
Date: 12-MAR-2022

Appendix 1 to DoC# TF-1001		
Applicable Standards and Guidelines		
Category	**Name**	**Number: Date Issued**
General	In Vitro Diagnostic Devices Directive	IVDD 98/79/EC: 1998
	Medical Devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Risk Analysis	Medical Devices – Application of risk management to medical devices	EN ISO 14971:2012
	Elimination or Reduction of Risk of Infection Related to In Vitro Diagnostic Reagents	EN 13641:2002
Labeling	In-vitro diagnostic medical devices – Information supplied by the manufacturer (Labeling). Part 1: Terms, definitions and general requirements. Part 2: In vitro diagnostic reagents for professional use	EN ISO 18113-1:2011 EN ISO 18113-2:2011
	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	BS EN ISO 15223-1:2016
Performance Evaluations	Performance evaluation of in vitro diagnostic medical devices	EN 13612:2002/AC:2002
	In Vitro Diagnostic Medical Devices—Evaluation of Stability of In Vitro Diagnostic Reagents	EN ISO 23640:2015
	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control material	EN ISO 17511:2003
Usability	Medical Devices – Applicability of usability engineering to Medical Devices	EN 62366-1:2015
Software	Medical Device Software – Software life cycle processes	EN 62304:2006 + A1:2015