

DECLARATION OF CONFORMITY

DoC#: TF-0502, Rev. R

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):

98100	Quidel Triage® D-Dimer Test
98100EU	Quidel Triage® D-Dimer Test
98831EU	Quidel Triage® D-Dimer Test

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

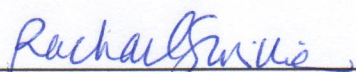
Management System: GQM, Quality Manual, Revision O

Quality System Certificate No: ISO 13485 Certificate QS2 040885 0029, Rev. 6,
Expires December 20, 2024

Conformity Pathway: Annex III

Classification: Article 9, Section 1, Other IVD

This Declaration of Conformity for the Quidel Triage® D-Dimer Test 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-0502		
Applicable Standards and Guidelines		
Category	Name	Number: Date Issued
General	In Vitro Diagnostic Device Directive	IVDD 98/79/EC:1998
	Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Risk	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 (labelling) – Part 1: Terms, definitions and general requirements	EN ISO 18113-1:2011
	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use	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
	In vitro diagnostic medical devices – Evaluation of stability of in vitro 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
	Medical devices - Application of usability engineering to medical devices	EN 62366-1:2015
Software	Medical device software – Software life-cycle processes	EN 62304:2006 + A1:2015