



Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

**Quidel Cardiovascular Inc.
9975 Summers Ridge Road
San Diego, CA 92121
UNITED STATES OF AMERICA**

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated November 28, 2018

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2018-11-28


Ludger Möller
President
MDSS GmbH

Annex A: November 28, 2018
Manufacturer: Quidel Cardiovascular Inc.

Model or Reference or Catalog or UDI Number	Device Trade/Brand Name (Notified)	Nomenclature (notified)	Nomenclature Code (Notified)	Nomenclature Description (Notified)	Class. (Notified)	EC Certificate No. & Expiry (Notified)	Registration Number
98100	Quidel Triage® D-Dimer Test	EDMA	13 02 05 03 00	D-Dimer	Other IVD	N/A	DE/CA09/0170/Q06/IVD/001-01
98100EU	Quidel Triage® D-Dimer Test	EDMA	13 02 05 03 00	D-Dimer	Other IVD	N/A	DE/CA09/0170/Q06/IVD/001-01
97000HS	Quidel Triage® Cardiac Panel	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
97000HSEU	Quidel Triage® Cardiac Panel	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
97300EU	Quidel Triage® Profiler SOB™ Panel	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
97400EU	Quidel Triage® Cardio3 Panel	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
97500EU	Quidel Triage® Cardio2 Panel	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
98600EU	Quidel Triage® Troponin I Test	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
97600EU	Quidel TriageTrue® High Sensitivity Troponin I Test	EDMA	12 13 01 90	Other Cardiac Markers	Other IVD	N/A	DE/CA09/0170/Q06/IVD/002-03
88753	Quidel Triage® Total 5 Control 1	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
88754	Quidel Triage® Total 5 Control 2	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
88755	Quidel Triage® Total 5 Calibration Verification	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98013XR	Quidel Triage® BNP Control 1	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03

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98014XR	Quidel Triage® BNP Control 2	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98015XR	Quidel Triage® BNP Calibration Verification	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98201	Quidel Triage® BNP QC Controls	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
88733	Quidel Triage® Total 3 Control 1	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
88734	Quidel Triage® Total 3 Control 2	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98713EU	Quidel Triage® NT-proBNP Control 1	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98714EU	Quidel Triage® NT-proBNP Control 2	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
97613EU	Quidel TriageTrue® High Sensitivity Troponin I Control 1	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
97614EU	Quidel TriageTrue® High Sensitivity Troponin I Control 2	EDMA	12 50 01 08 00	Cardiac Marker Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/005-03
98000XR	Quidel Triage® BNP Test	EDMA	12 13 01 01	BNP / proBNP (including other Natriuretic Peptides)	Other IVD	N/A	DE/CA09/0170/Q06/IVD/003-02
98000XREU	Quidel Triage® BNP Test	EDMA	12 13 01 01	BNP / proBNP (including other Natriuretic Peptides)	Other IVD	N/A	DE/CA09/0170/Q06/IVD/003-02
98200	Quidel Triage® BNP Reagents	EDMA	12 13 01 01	BNP / proBNP (including other Natriuretic Peptides)	Other IVD	N/A	DE/CA09/0170/Q06/IVD/003-02
98700EU	Quidel Triage® NT-proBNP Test	EDMA	12 13 01 01	BNP / proBNP (including other Natriuretic Peptides)	Other IVD	N/A	DE/CA09/0170/Q06/IVD/003-02

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98202	Quidel Triage® BNP Calibrators	EDMA	12 50 01 07 00	Cardiac Marker Standards and Calibrators	Other IVD	N/A	DE/CA09/0170/Q06/IVD/004-01
55070	Quidel Triage® MeterPro	EDMA	21 07 11 09	Other POC Hardware + acc + cons + software	Other IVD	N/A	DE/CA09/0170/Q06/IVD/008-01
55071	Quidel Triage® MeterPro	EDMA	21 07 11 09	Other POC Hardware + acc + cons + software	Other IVD	N/A	DE/CA09/0170/Q06/IVD/008-01
94400	Quidel Triage® TOX Drug Screen	EDMA	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Test	Other IVD	N/A	DE/CA09/0170/Q06/IVD/006-01
94401	Quidel Triage® TOX Drug Screen	EDMA	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Test	Other IVD	N/A	DE/CA09/0170/Q06/IVD/006-01
94402	Quidel Triage® TOX Drug Screen	EDMA	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Test	Other IVD	N/A	DE/CA09/0170/Q06/IVD/006-01
94404	Quidel Triage® TOX Drug Screen	EDMA	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Test	Other IVD	N/A	DE/CA09/0170/Q06/IVD/006-01
94400EU	Quidel Triage® TOX Drug Screen	EDMA	12 70 09 70 00	Multiple Drugs of Abuse/Toxicology Rapid Test	Other IVD	N/A	DE/CA09/0170/Q06/IVD/006-01
94413	Quidel Triage® TOX Drug Screen Control 1	EDMA	12 50 01 02 00	TDM/Drug Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/007-01
94414	Quidel Triage® TOX Drug Screen Control 2	EDMA	12 50 01 02 00	TDM/Drug Controls	Other IVD	N/A	DE/CA09/0170/Q06/IVD/007-01
98800EU	Quidel Triage® PLGF Test	EDMA	12 05 02 90 00	Other Pregnancy Testing Hormones	Other IVD	N/A	DE/CA09/0170/Q06/IVD/010-01

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98813EU	Quidel Triage® PLGF Control 1	EDMA	12 50 01 90 00	Other Controls Immunochemistry	Other IVD	N/A	DE/CA09/0170/Q06/IVD/009-01
98814EU	Quidel Triage® PLGF Control 2	EDMA	12 50 01 90 00	Other Controls Immunochemistry	Other IVD	N/A	DE/CA09/0170/Q06/IVD/009-01