



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 Corporation
10165 McKellar Ct.
San Diego CA 92121
USA**

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 2021-12-20

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.

2021-12-20

Dr. Philipp Hohenbrink
Director AR Services
MDSS GmbH

Annex A: 2021-12-20

Manufacturer: Quidel Corporation, 10165 McKellar Ct., San Diego 92121, USA

REF	Device Names (notified)	Additional Info. (optional)	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
20282	Sofia Quantitative Vitamin D FIA		12 06 03 10	25-Hydroxyvitamin D	"Other"	N/A	DE/CA09/0170/Q07/IVD/008
20327	Sofia Quantitative Vitamin D		12 50 01 12	Anaemia Related/Vitamin Controls	"Other"	N/A	DE/CA09/0170/Q07/IVD/007
RPS-DESTD	InflammaDry® External Controls		12 50 01 90 00	Other Specific Controls - Immunochemistry	"Other"	N/A	DE/CA09/0170/Q07/IVD/010
RPS-ID-20 RPS-ID-20-U	InflammaDry®		12 70 01 90 00	Other Specific Proteins Rapid Tests	"Other"	N/A	DE/CA09/0170/Q07/IVD/012
20110 20110IN	QuickVue® hCG Combo Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/015
00178 00179	QuickVue®+ One Step hCG Combo Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/015
20109 20109IN 20109SC	QuickVue® hCG Urine Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/015
20229 20266	Sofia® hCG FIA		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/015
20309	Sofia 2 Lyme+ FIA		15 01 06 03	Lyme Antibody Total	"Other"	N/A	DE/CA09/0170/Q07/IVD/009
20329	Sofia®2 C. difficile FIA		15 01 16 03	C. difficile GDH and toxin A/B combined detection	"Other"	N/A	DE/CA09/0170/Q07/IVD/022
20183 20183IN	QuickVue® Influenza A+B Test		15 04 80 04 00	Influenza & Para Influenza	"Other"	N/A	DE/CA09/0170/Q07/IVD/005
00317 00317IN	QuickVue® Influenza Test		15 04 80 04 00	Influenza & Para Influenza	"Other"	N/A	DE/CA09/0170/Q07/IVD/005
20218 20254	Sofia Influenza A+B FIA		15 04 80 04 00	Influenza & Para Influenza	"Other"	N/A	DE/CA09/0170/Q07/IVD/005
20374	Sofia® SARS Antigen FIA		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/Q07/IVD/017
20378	Sofia® SARS Antigen FIA		15 04 80 19	Coronavirus	"Other"	N/A	DE/CA09/0170/Q07/IVD/017
20412	Savanna™ RVP4 Assay	12 cartridges/ assays/ 4- panels	15 30 02 42	Influenza & Para Influenza / Respiratory Syncytial Virus (RSV) / SARS-CoV - Multiplex NA Reagents	"Other"	N/A	DE/CA09/0170/Q07/IVD/021

Annex A: 2021-12-20

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REF	Device Names (notified)	Additional Info. (optional)	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
20380	Sofia®2 Flu + SARS Antigen FIA		15 30 02 70	Other Multiple Viruses - Multiplex Assays	"Other"	N/A	DE/CA09/0170/Q07/IVD/018
20391	Sofia®2 Flu + SARS Antigen FIA Ctrl Swab Set		15 50 01 04	Other Virology Controls - Inf.Imm.	"Other"	N/A	DE/CA09/0170/Q07/IVD/019-02
20384	Sofia® SARS Antigen FIA Ctrl Swab Set		15 50 01 04	Other Virology Controls - Inf.Imm.	"Other"	N/A	DE/CA09/0170/Q07/IVD/019-02
20389	QuickVue® SARS Antigen Test Ctrl Swab Set		15 50 01 04	Other Virology Controls - Inf.Imm.	"Other"	N/A	DE/CA09/0170/Q07/IVD/019-02
0B006	QuickVue® Chlamydia Test		15 70 01 01	Chlamydia Ag - Rapid Test	Annex II -List B	0123/V1 040885 0032 exp. 2024-05-26	DE/CA09/0170/Q07/IVD/001-01
0W009 0W010 20101	QuickVue® H. pylori Test		15 70 01 02 00	H. Pylori - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/004
00343 00343IN 00343SC	QuickVue® In-Line Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/014
20108 20108IN 20125	QuickVue® Dipstick Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/014
20122 20122IN 20122SC	QuickVue® + Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/014
20231 20253	Sofia Strep A FIA		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/014

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20274 20276	Sofia Strep A+ FIA		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/014
20244	Sofia Legionella FIA		15 70 01 08	Legionella - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/016
20293	Sofia® S. pneumoniae FIA		15 70 01 09	Strep. Pneumoniae - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/006
20222 20224	QuickVue® RSV 10 Test		15 70 90 02 00	RSV - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/003
20193 20199	QuickVue® RSV Test		15 70 90 02 00	RSV - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/003
20242 20260	Sofia RSV FIA		15 70 90 02 00	RSV - Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/003
20121 20121SC	QuickVue+® Mononucleosis Test		15 70 90 03 00	Mononucleosis Rapid Test	"Other"	N/A	DE/CA09/0170/Q07/IVD/002
20396	QuickVue® SARS Antigen Test		15 70 90 08	Coronavirus, RT & POC	"Other"	N/A	DE/CA09/0170/Q07/IVD/020-02
20375 20379	Sofia® 2 SARS-CoV-2 Antibody IgG FIA		15 70 90 08	Coronavirus, RT & POC	"Other"	N/A	DE/CA09/0170/Q07/IVD/020-02
RPS-AD NIC-AD	AdenoPlus®		15 70 90 90 00	Other Other Virology Rapid Tests	"Other"	N/A	DE/CA09/0170/Q07/IVD/011
20221 20221R	Sofia Analyzer		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	DE/CA09/0170/Q07/IVD/013
20230	Sofia Installation Pack		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	DE/CA09/0170/Q07/IVD/013
20299 20299R 20300 203000R	Sofia® 2	Analyzer	21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	DE/CA09/0170/Q07/IVD/013
20314	Sofia® 2 Installation Pack		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	DE/CA09/0170/Q07/IVD/013