



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 2021-08-16

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.

2021-08-16

Ludger Möller
President
MDSS GmbH

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
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-tests)	15 30 02 42	Influenza & Para Influenza / Respiratory Syncytial Virus (RSV) /	"Other"	N/A	DE/CA09/0170/Q07/IVD/021
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

Annex A: 2021-08-16

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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
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
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

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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