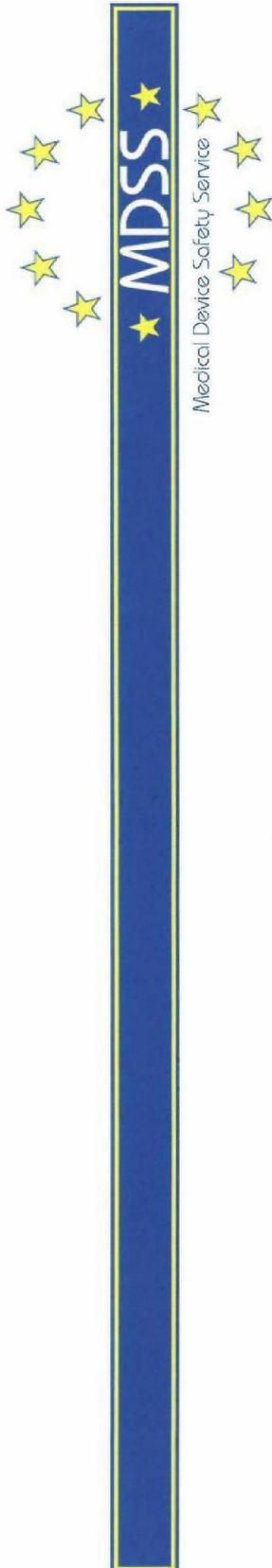


Certificate of CE-Registration



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

5.1.2e

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 2020-06-25

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.

2020-06-25

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MDSS GmbH

Annex A: 2020-06-25

Manufacturer: Quidel Corporation, 5.1.2e

REF	Device Names (notified)	Additional Info. (optional)	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
20293	Sofia® S. pneumoniae FIA		15 70 01 09	Strep. Pneumoniae - Rapid Test	"Other"	N/A	5.1.5
20244	Sofia Legionella FIA		15 70 01 08	Legionella - Rapid Test	"Other"	N/A	
20183 20183IN 20185	QuickVue® Influenza A+B Test		15 04 80 04	Influenza & Para influenza	"Other"	N/A	
00317 00317IN	QuickVue® Influenza Test		15 04 80 04	Influenza & Para Influenza	"Other"	N/A	
20218 20254	Sofia Influenza A+B FIA		15 04 80 04	Influenza & Para influenza	"Other"	N/A	
0W009 0W010 20101	QuickVue® H. pylori Test		15 70 01 02 00	H. Pylori - Rapid Test	"Other"	N/A	
20222 20224	QuickVue® RSV 10 Test		15 70 90 02	RSV - Rapid Test	"Other"	N/A	
20193 20199	QuickVue® RSV Test		15 70 90 02	RSV - Rapid Test	"Other"	N/A	
20242 20260	Sofia RSV FIA		15 70 90 02	RSV - Rapid Test	"Other"	N/A	
20121 20121SC	QuickVue+® Mononucleosis Test		15 70 90 03 00	Mononucleosis Rapid Test	"Other"	N/A	
08006	QuickVue® Chlamydia Test		15 70 01 01	Chlamydia Ag - Rapid Test	Annex II -List B	0123/ V1 15 40885 020 - 23.11.2020	
20110 20110IN	QuickVue® hCG Combo Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	
00178 00179	QuickVue®+ One Step hCG Combo Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	
20109 20109IN 20109SC	QuickVue® hCG Urine Test		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	
20229 20266	Sofia® hCG FIA		12 70 05 02 00	HCG - Rapid Test	"Other"	N/A	

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Annex A: 2020-06-25

Manufacturer: Quidel Corporation, 5.1.2e

REF	Device Names (notified)	Additional Info. (optional)	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
00343 00343IN 00343SC	QuickVue® In-Line Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	5.1.5
20108 20108IN 20125 20108SC	QuickVue® Dipstick Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	
20122 20122IN 20122SC	QuickVue® + Strep A Test		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	
20231 20253	Sofia Strep A FIA		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	
20274 20276	Sofia Strep A+ FIA		15 70 01 03 00	Strep A Rapid Test	"Other"	N/A	
20221 20221R	Sofia Analyzer		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	
20230	Sofia Installation Pack		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	
20299 20299R 20300 20300OR	Sofia® 2	Analyzer	21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	
20314	Sofia® 2 Installation Pack		21 02 10 01	IC & II Hardware + Accessories + Consumables + Software	"Other"	N/A	
RPS-ID-20 RPS-ID-20-U	InflammaDry®		12 70 01 90 00	Other Specific Proteins Rapid Tests	"Other"	N/A	
RPS-AD NIC-AD	AdenoPlus®		15 70 90 90 00	Other Other Virology Rapid Tests	"Other"	N/A	
RPS-DESTD	InflammaDry® External Controls		12 50 01 90 00	Other Specific Controls - Immunochemistry	"Other"	N/A	
20309	Sofia 2 Lyme+ FIA		15 01 06 03	Lyme Antibody Total	"Other"	N/A	
20282	Sofia Quantitative Vitamin D FIA		12 06 03 10	25-Hydroxyvitamin D	"Other"	N/A	

5.1.2e



Annex A: 2020-06-25

Manufacturer: Quidel Corporation, 5.1.2e

REF	Device Names (notified)	Additional Info. (optional)	EDMA Code (notified)	EDMA Description (notified)	Class. (notified)	EC Certificate No. & Expiry (notified)	German Registration Number
20327	Sofia Quantitative Vitamin D Control Set		12 50 01 12	Anaemia Related/Vitamin Controls	"Other"	N/A	5.1.5
20374	Sofia® SARS Antigen FIA		15 04 80 19	Coronavirus	"Other"	N/A	
20378	Sofia® SARS Antigen FIA		15 04 80 19	Coronavirus	"Other"	N/A	

5.1.2e

