

CE DECLARATION OF CONFORMITY **According to Annex III of the IVD Directive 98/79/EC**

MANUFACTURER

ELITech MICROBIO
 Parc d'activités du plateau - Allée d'Athènes
 83870 SIGNES (France)

REF.	DESCRIPTION	REF.	DESCRIPTION
00014	SEROLOGY (14 tests)	23000	RAPID POLYMYXIN NP (10 tests)
00036	MYCOFAST® EvolutionN 3 (25 tests)	23001	RAPID POLYMYXIN PSEUDOMONAS (10 tests)
00050	MYCOFAST US (30 tests)	23002	RAPID POLYMYXIN ACINETOBACTER (10 tests)
00060	MYCOFAST® RevolutionN (25 tests)	23005	SUPERPOLYMYXIN (20 tests)
00061	UMMT RevolutionN (50 tests)	44030	CANDIFAST (30 tests)
00062	COMPL. MYCOFAST® RevolutionN (25 tests)	44130	CANDIFAST Es Twin (30 tests)
00063	MYCOFAST® Screening RevolutionN (50 tests)	44412	FUNGIFAST® AFG (12 tests)
00070	MYCOFAST® RevolutionN ATB+ (25 tests)	44430	FUNGIFAST (30 tests)
00073	COMPL. MYCOFAST® RevolutionN ATB+ (25 tests)	44500	ELITex Bicolor albi-dubli (60 tests)
00077	UMMt-UMMlyo 3 ml (35 tests)	44502	ELITex Bicolor dubliniensis (100 tests)
00080	MYCOFAST® RevolutionN 2 (25 tests)	44504	ELITex krusei (30 tests)
00081	MYCOFAST® RevolutionN 2 AMIES (25 tests)	44506	ELIchrom glabrata (40 tests)
00082	COMPL. MYCOFAST® RevolutionN 2 (25 tests)	44600	ELI.H.A Candida (120 tests or 20 reactions of 6 dilutions)
00083	UMMt AMIES RevolutionN (50 tests)	44602	ELI.H.A Aspergillus (102 tests or 17 reactions of 6 dilutions)
00084	MYCOFAST Screening PLUS	66600	ELI.H.A Schistosoma (120 tests or 20 reactions of 6 dilutions)
00085	MYCOFAST Screening PLUS UMMt	66602	ELI.H.A Amoeba (120 tests or 20 reactions of 6 dilutions)
00086	MYCOFAST Screening PLUS UMMt AMIES	66604	ELI.H.A Echinococcus (102 tests or 17 reactions of 6 dilutions)
00090	A7 AGAR (8 tests)	66606	ELI.H.A Distoma (102 tests or 17 reactions of 6 dilutions)
00836	UMMt 3ml (35 tests)	66608	ELITex Bicolor Amoeba (25 tests)
00900	MYCOPLASMA CONTROL (12 tests)	482200	Amibiase HAI / IHA Amoebiasis Fumouze (120 tests)
04115	ELI.H.A RF (220 tests)	500400	Staph aureus Fumouze® (60 tests)
04135	DOR-BAR WITH CONTROL + (12 tests)	514000	Bilharziose / Schistosomiasis Fumouze (120 tests)
04145	Strepto-Color (50 tests)	513400	Candidose / Candidiasis Fumouze (120 tests)
04155	ELITEX BICOLOR MONO (50 tests)	522600	MNI Test Fumouze® (40 tests)
04156	ELITEX BICOLOR MONO (100 tests)	523200	Polyartest Fumouze® (25 tests)
04165	ELITEX BICOLOR RF (50 tests)	523800	Streptozyme Fumouze® (50 tests)
04166	ELITEX BICOLOR RF (100 tests)	524400	Aspergillose / Aspergillosis Fumouze (102 tests)
04175	WAALER ROSE BICOLOR (50 tests)	524600	Distomatose / Distomiasis Fumouze® (102 tests)
04176	WAALER ROSE BICOLOR (100 tests)	524700	Bichro-Latex albicans Fumouze (60 tests)
08000	CIQ CIL TEST DE LA SUEUR (20 tests)	524800	Hydatidose / Echinococcosis Fumouze® (102 tests)
22297	URIFAST 2 (20 tests)	534000	Bichro-latex amibe Fumouze (25 tests)
22711	ELITex STAPH (60 tests)	535600	Polyartitre Fumouze® (220 tests)
22712	ELITex STAPH (160 tests)	556000	Rhumalate Fumouze® (60 tests)
		536600	Mono-Diff Fumouze® (20 tests)
		683400	Staph aureus Fumouze® (160 tests)

We undersigned, ELITech MICROBIO, hereby declare that the above-mentioned devices (non-listed in Annex II) comply with all essential requirements (Annex I) and declare to fulfill the obligations imposed by Annex III – Section 2-5 of the Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices.

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Signes, 18th May 2022
Stéfan LAMOUROUX, Managing Director
 ELITech MICROBIO