

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

MANUFACTURER
 ELITech MICROBIO
 Parc d'activités du plateau - 19 allée d'Athènes
 83870 SIGNES (France)

REF.	DESCRIPTION	REF.	DESCRIPTION
00014	SEROLOGY (14 tests)	44412	FUNGIFAST® AFG (12 tests)
00025	MYCOSCREEN PLUS (32 tests)	44430	FUNGIFAST (30 tests)
00031	MYCOFAST® Evolution 2 (30 tests)	44328	ELIchrom Fungi (25 tests)
00036	MYCOFAST® Evolution 3 (25 tests)	44329	ELIchrom Fungi Code Book (1 CD-ROM)
00042	MYCOFAST® Screening Evolution 3 (35 tests)	RPRL-0100	RPRL VDRL CARBON
00043	MYCOFAST® Screening xp (35 tests)	04115	ELI.H.A RF (220 tests or 20 reactions of 11 dilutions)
00060	MYCOFAST® Revolution (25 tests)	04145	Strepto-Color (50 tests)
00061	UMMt Revolution (50 tests)	04155	ELITEX BICOLOR MONO (50 tests)
00062	COMPL. MYCOFAST® Revolution (25 tests)	04156	ELITEX BICOLOR MONO (100 tests)
00063	MYCOFAST® Screening Revolution (50 tests)	04165	ELITEX BICOLOR RF (50 tests)
00064	MYCOPLASMA STABILIZER 2x5mL (100 tests)	04166	ELITEX BICOLOR RF (100 tests)
00070	MYCOFAST® Revolution ATB+ (25 tests)	04175	WAALER ROSE BICOLOR (50 tests)
00073	COMPL. MYCOFAST® Revolution ATB+ (25 tests)	04176	WAALER ROSE BICOLOR (100 tests)
00080	MYCOFAST® Revolution 2 (25 tests)	22711	ELITex STAPH (60 tests)
00081	MYCOFAST® Revolution 2 AMIES (25 tests)	22712	ELITex STAPH (160 tests)
00082	COMPL. MYCOFAST® Revolution 2 (25 tests)	44500	ELITex Bicolor albi-dubli (60 tests)
00083	UMMt AMIES Revolution (50 tests)	44501	ELITex Bicolor albi-dubli (360 tests)
00074	UMMt-UMMlyo 2ml (35 tests)	44502	ELITex Bicolor dubliniensis (100 tests)
00077	UMMt-UMMlyo 3 ml (35 tests)	44504	ELITex krusei (30 tests)
00090	A7 AGAR (8 tests)	44506	ELIchrom glabrata (40 tests)
00097	SEROLOGY (120 tests)	44600	ELI.H.A Candida (120 tests or 20 reactions of 6 dilutions)
00835	UMMt 2ml (35 tests)	44602	ELI.H.A Aspergillus (102 tests or 17 reactions of 6 dilutions)
00836	UMMt 3ml (35 tests)	66600	ELI.H.A Schistosoma (120 tests or 20 reactions of 6 dilutions)
00900	MYCOPLASMA CONTROL (12 tests)	66602	ELI.H.A Amoeba (120 tests or 20 reactions of 6 dilutions)
00905	CLOSING SYSTEM (250 covers)	66604	ELI.H.A Echinococcus (102 tests or 17 reactions of 6 dilutions)
04125	ASO-BAR WITH CONTROL + (12 tests)	66606	ELI.H.A Distoma (102 tests or 17 reactions of 6 dilutions)
04135	DOR-BAR WITH CONTROL + (12 tests)	66608	ELITex Bicolor Amoeba (25 tests)
04905	COMPLEMENT ASO-BAR (16 tests)	66700	ELIstain Kop-Color (100 tests)
22204	PRESTO ABG	66702	ELIstain Paratest (100 tests)
22214	URIFAST® ABG® V2 (50 tests)	23000	RAPID POLYMYXIN NP (10 tests)
22296	URIFAST® Twin 1C V2 (50 tests)	23001	RAPID POLYMYXIN PSEUDOMONAS (10 tests)
44008	CANDIFAST (8 tests)	23002	RAPID POLYMYXIN ACINETOBACTER (10 tests)
44030	CANDIFAST (30 tests)	23005	SUPERPOLYMYXIN (20 tests)
44130	CANDIFAST Es Twin (30 tests)		
44212	CANDICHROM II Pack 4x180ml (48 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.

ELITECH MICROBIO
 Parc d'activités du Plateau
 19, allée d'Athènes - 83870 SIGNES
 Tél. : 04 94 88 55 00 - Fax 04 94 88 55 03
 SAS au Capital de 480 864 €
 Siret 503 366 239 00021 - A.N.E 4675 Z

Signes, 10th March 2020
 Stelian LAMOUROUX, Managing Director

