

Parc d'Activités • 19 Allée d'Athènes
83870 Signes • France

TEL: +33 (0)4 94 88 55 00

FAX: +33 (0)4 94 88 55 05

elitechmicrobio@elitechgroup.com

www.elitechgroup.com

CE DECLARATION OF CONFORMITY

According to Annex III of the IVD Directive 98/79/EC

MANUFACTURER & PRODUCTION SITE

ELITech MICROBIO

Parc d'activités, allée d'Athènes

83870 SIGNES (France)

REF.	DESCRIPTION	REF.	DESCRIPTION
00014	SEROLOGY (14 tests)	04115	ELI.H.A RF (220 tests or 20 reactions of 11 dilutions)
00025	MYCOSCREEN PLUS (32 tests)	04145	Strepto-Color (50 tests)
00031	MYCOFAST® Evolution 2 (30 tests)	04145	Strepto-Color (50 tests) - NEW!
00036	MYCOFAST® Evolution 3 (25 tests)	04155	ELITEX BICOLOR MONO (50 tests)
00042	MYCOFAST® Screening Evolution 3 (35 tests)	04156	ELITEX BICOLOR MONO (100 tests)
00043	MYCOFAST® Screening xp (35 tests)	04165	ELITEX BICOLOR RF (50 tests)
00060	MYCOFAST® Revolution (25 tests)	04166	ELITEX BICOLOR RF (100 tests)
00061	UMMT Revolution (50 tests)	04175	WAALER ROSE BICOLOR (50 tests)
00062	COMPL. MYCOFAST® Revolution (25 tests)	04176	WAALER ROSE BICOLOR (100 tests)
00063	MYCOFAST® Screening Revolution (50 tests)	22711	ELITex STAPH (60 tests)
00064	MYCOPLASMA STABILIZER 2x5mL (100 tests)	22712	ELITex STAPH (160 tests)
00074	UMMt-UMMIyo 2ml (35 tests)	44500	ELITex Bicolor albi-dubli (60 tests)
00077	UMMt-UMMIyo 3 ml (35 tests)	44501	ELITex Bicolor albi-dubli (360 tests)
00090	A7 AGAR (8 tests)	44502	ELITex Bicolor dubliniensis (100 tests)
00835	UMMt 2ml (35 tests)	44504	ELITex krusei (30 tests)
00836	UMMt 3ml (35 tests)	44506	ELIchrom glabrata (40 tests)
00900	MYCOPLASMA CONTROL (12 tests)	44600	ELI.H.A Candida (120 tests or 20 reactions of 6 dilutions)
00905	CLOSING SYSTEM (250 covers)	44602	ELI.H.A Aspergillus (102 tests or 17 reactions of 6 dilutions)
04125	ASO-BAR WITH CONTROL + (12 tests)	66600	ELI.H.A Schistosoma (120 tests or 20 reactions of 6 dilutions)
04135	DOR-BAR WITH CONTROL + (12 tests)	66602	ELI.H.A Amoeba (120 tests or 20 reactions of 6 dilutions)
04905	COMPLEMENT ASO-BAR (16 tests)	66604	ELI.H.A Echinococcus (102 tests or 17 reactions of 6 dilutions)
22214	URIFAST® ABG® V2 (50 tests)	66606	ELI.H.A Distoma (102 tests or 17 reactions of 6 dilutions)
22221	URICHROM II 20 tests	66608	ELITex Bicolor Amoeba (25 tests)
22296	URIFAST® Twin 1C V2 (50 tests)	66700	ELIstain Kop-Color (100 tests)
22800	ELIchrom Coryne (12 tests)	66702	ELIstain Paratest (100 tests)
22801	ELIchrom Coryne Code Book (1 CD-ROM)		
44030	CANDIFAST (30 tests)		
44130	CANDIFAST Es Twin (30 tests)		
44212	CANDICHROM II Pack 4x180ml (48 tests)		
44328	ELIchrom Fungi (25 tests)		
44412	FUNGIFAST® AFG (12 tests)		
44430	FUNGIFAST (30 tests)		
44329	ELIchrom Fungi Code Book (1 CD-ROM)		
RPRL-0100	RPRL VDRL CARBON		
TPHA-0100	TPHA		
TPHA-0004	TPHA 5 MICROPLATES		

We undersigned, ELITech MICROBIO, hereby declare that the above-mentioned devices 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.

Signes, 14th April 2015

ELITech MICROBIO David Salom, Managing Director, ELITech MICROBIO

Parc d'activités du Plateau
19, allée d'Athènes - 83870 SIGNES
Tél. : 04 94 88 55 00 - Fax 04 94 88 55 05
SAS au Capital de 480 864 €
Siret 503 366 239 00021 - APE 4675 Z

