



Biolife Italiana S.r.l

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Certified Quality System
ISO 13485:2016
Cert. n° D2001500012
ISO 9001:2015
Cert. n° D2001500013



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EC Declaration of Conformity to In Vitro Diagnostic Medical Devices Directive 98/79/EC according to Annex III of the IVDD

Biolife Italiana Srl
Viale Monza 272, 20128 Milan

declares that diagnostic reagents listed on the attached Device Schedule, classified as IVD Medical Devices, conform to the relevant provisions of the EC Council Directive 98/79/EC and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

Biolife Italiana Srl agrees to develop, implement and maintain a documented postproduction experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Biolife Italiana Srl confirms that no medicinal products/drugs are incorporated in any device covered by the Device Schedule

Biolife Italiana Srl
Dr Massimo Brunelli

BIOLIFE ITALIANA s.r.l.
20128 MILANO - Viale Monza, 272
Part. IVA 01149250159

Managing Director

Milan, May 10, 2017

CE_DECLARATION_BL_05-2017-REV.8



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DEVICE SCHEDULE

REF N° DEVICE COMMERCIAL NAME

DEHYDRATED CULTURE MEDIA FOR MICROBIOLOGY

EDMA CLASS. 14 01 01 01 / 14 03 01 01

4010344	AMIES TRANSPORT MEDIUM -5KG
4010342	AMIES TRANSPORT MEDIUM-500G
4010492	ANTIBIOGRAMMA BASE AGAR-500G
4010494	ANTIBIOGRAMMA BASE AGAR-5KG
4011002	AZIDE BLOOD AGAR BASE -500G
4011102	AZIDE VIOLET BLOOD AGAR BASE-500G
4011454	BIOTONE -TRYPTOSE AGAR -5 KG
4011452	BIOTONE -TRYPTOSE AGAR -500G
4011464	BIOTONE -TRYPTOSE BROTH -5 KG
4011462	BIOTONE -TRYPTOSE BROTH -500G
40121022	BISMUTH SULPHITE AGAR USP-500G
4011552	BLOOD AGAR BASE -500G
4011554	BLOOD AGAR BASE -5KG
4011564	BLOOD AGAR BASE N. 2 - 5KG
4011562	BLOOD AGAR BASE N°2 -500G
4012152	BORDET GENGOU AGAR BASE
4012352	BRAIN HEART INFUSION AG-500G
4012354	BRAIN HEART INFUSION AGAR-5KG
4012302	BRAIN HEART INFUSION BR-500G
4012304	BRAIN HEART INFUSION BR-5KG
4012742	BRUCELLA BROTH -500G
4012752	BRUCELLA MEDIUM BASE -500G
4012832	CAMPY. BLOOD FREE MEDIUM BASE -KARMALI-500G
4012852	CAMPY..BLOOD AGAR BASE -500G
4012802	CANDIDA AGAR (NICKERSON) -500G
4012872	CARY BLAIR TRANSPORT MEDIUM
4013002	CHAPMAN-STONE MEDIUM -500G
4080001	CHROMALBICANS AGAR - 100G
4080002	CHROMALBICANS AGAR - 500G
4080102	CHROMART STREPTO B BASE
4080252	CHROMART CRE-ESBL BASE
4080052	CHROMOGENIC CANDIDA AGAR (CCA)
4055811	CHROMOGENIC E.COLI 0157 AGAR -100G
4055812	CHROMOGENIC E.COLI 0157 AGAR -500G
4053501	CHROMOGENIC SALMONELLA AG.BASE-100G
4053502	CHROMOGENIC SALMONELLA AG.BASE-500G
4098101	CHROMOGENIC URINE AGAR II -100G
4098102	CHROMOGENIC URINE AGAR II -500G
409810G1	CHROMOGENIC URINE AGAR IV -100G
409810G2	CHROMOGENIC URINE AGAR IV -500G
4013022	CIN AGAR BASE -500G
40129012	CLED MEDIUM -500G
40129014	CLED MEDIUM -5KG
4013082	CLOSTRIDIUM DIFFICILE AGAR BASE-500G
4011362	COLUMBIA AGAR BASE -500G
4011364	COLUMBIA AGAR BASE -5KG
40113614	COLUMBIA CNA AGAR BASE- 5 KG
40113612	COLUMBIA CNA AGAR BASE-500G
40133112	CPLM SELECTIVE WITH CAF-500G
4013312	CPLM TRICHOMONAS BROTH-500G
4013672	DECARBOXYLASE FALKOW BASE BROTH-500G
4013662	DECARBOXYLASE MOELLER BASE BROTH-500G



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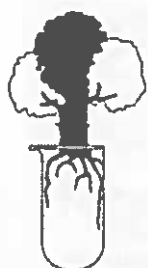
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40136912	DERMATOPHYTE SELECTIVE MEDIUM -500G
4013702	DESOXYCHOLATE AGAR -500G
4013752	DESOXYCHOLATE CITRATE AGAR -500G
4013682	DESOXYRIBONUCLEASE TEST MEDIUM -500G
4015242	G N BROTH HAJNA -500G
4015202	GC MEDIUM BASE -500G
4015204	GC MEDIUM BASE -5KG
4015352	HEART INFUSION AGAR -500G
4015402	HEART INFUSION BROTH -500G
4015412	HEKTOEN ENTERIC AGAR -500G
4015414	HEKTOEN ENTERIC AGAR -5KG
4015432	HERELLEA AGAR -500G
4015452	INDOLE NITRATE BROTH -500G
401634	IUT MEDIUM
4015602	KLIGLER IRON AGAR -500G
4015822	LEGIONELLA BCYE AGAR BASE - 500 G
4015952	LEVINE EMB BLUE AGAR -500G
4015954	LEVINE EMB BLUE AGAR -5KG
4016352	LOWENSTEIN-JENSEN MEDIUM BASE-500G
4016422	LUXURIAN AGAR (EUGONIC) -500G
4016432	LUXURIAN BROTH (EUGONIC) -500G
4016362	LYSINE IRON AGAR -500G
4017434	M. K. TETRATHIONATE BROTH -5 KG
4017432	M. K. TETRATHIONATE BROTH -500G
4016704	MAC CONKEY AGAR - 5KG
4016702	MAC CONKEY AGAR -500G
4016724	MAC CONKEY AGAR MUG - 5KG
4016722	MAC CONKEY AGAR MUG -500G
401669S2	MAC CONKEY SORBITOL AGAR -500G
4016692	MAC CONKEY SORBITOL MUG AGAR -500G
4016852	MALONATE BROTH -500G
4016652	MANNITOL SALT AGAR -500G
4016654	MANNITOL SALT AGAR -5KG
4017352	MRVP MEDIUM -500G
4017402	MULLER HINTON AGAR II -500G
4017404	MULLER HINTON AGAR II -5KG
4017412	MULLER HINTON BROTH -500G
4017602	MYCOBIOS AGAR -500G
4017612	MYCOBIOS SELECTIVE AGAR -500G
4018104	NUTRIENT AGAR - 5KG
4018102	NUTRIENT AGAR -500G
4018154	NUTRIENT BROTH - 5KG
4018152	NUTRIENT BROTH -500G
4018202	NUTRIENT GELATIN -500G
4018362	O/F HUGH LEIFSON BASE -500G
4019052	PHENOL RED AGAR BASE -500G
4019102	PHENOL RED BROTH BASE -500G
4019162	PHENYLALANINE AGAR -500G
4019612	PSEUDOMONAS AGAR F -500G
4019622	PSEUDOMONAS AGAR P -500G
4019632	PSEUDOMONAS SELECTIVE AGAR -500G
4019712	PURPLE LACTOSE AGAR -500G
4019804	RAPPAPORT VASSILIADIS BROTH - 5KG
4019802	RAPPAPORT VASSILIADIS BROTH -500G
4019852	ROGOSA BIOS AGAR -500G
4019902	ROGOSA BIOS BROTH -500G
4020062	SABOURAUD DEX.AGAR W/CAF 50 -500G
4020072	SABOURAUD DEXT.AGAR CAF 500MG -500G
4020054	SABOURAUD DEXTROSE AGAR - 5KG
4020052	SABOURAUD DEXTROSE AGAR -500G
4020064	SABOURAUD DEXTROSE AGAR W/CAF50-5KG
4020102	SABOURAUD MALTOSE AGAR -500G
4020104	SABOURAUD MALTOSE AGAR -5KG
4020254	SELENITE BROTH - 5KG



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4020252	SELENITE BROTH -500G
402025B4	SELENITE BROTH BASE -5KG
402025B2	SELENITE BROTH BASE -500G
4020362	SIM BIOS MEDIUM -500G
4020452	SIMMONS CITRATE AGAR -500G
4020482	SLANETZ BARTLEY AGAR -500G
4020472	SLANETZ BARTLEY AGAR W/O TTC -500G
4020754	SS AGAR - 5KG
4020752	SS AGAR -500G
4020852	STAPHYLOCOCCI 110 MEDIUM -500G
4020872	STREPTOCOCCUS SELECTIVE AGAR -500G
4020882	STREPTOCOCCUS SELECTIVE BROTH-500G
4020912	STUART TRANSPORT MEDIUM -500G
401367L	TAYLOR LYSINE DECARBOXYLASE BROTH
4021062	TCBS KOBAYASHI AGAR -500G
4021064	TCBS KOBAYASHI AGAR -5KG
4021374	THIOGLYCOLLATE MEDIUM - 5KG
4021372	THIOGLYCOLLATE MEDIUM -500G
4021342	TODD-HEWITT BROTH -500G
4021412	TRIPLE SUGAR IRON AGAR U.S.P.-500G
4021504	TRYPTIC SOY AGAR - 5KG
4021502	TRYPTIC SOY AGAR -500G
4021514	TRYPTIC SOY BLOOD AGAR BASE - 5KG
4021512	TRYPTIC SOY BLOOD AGAR BASE -500G
4021554	TRYPTIC SOY BROTH - 5KG
4021552	TRYPTIC SOY BROTH -500G
4021752	UREA AGAR BASE-CHRISTENSEN -500G
4021802	UREA BROTH BASE-STUART -500G
4021832	VERA CTSA MEDIUM -500G
4021922	VOGEL-JOHNSON AGAR -500G
4022002	WURTZ AGAR-500G
4022062	XLD AGAR -500G
4022064	XLD AGAR -5KG

ADDITIVE FOR CULTURE MEDIA

EDMA CLASS. 14 01 01 04

4240009	BIOVITEX/RESTORING FLUID
42185011	BIOVITEX/RESTORING FLUID
4240015	BLASER WANG ANTIMICROBIC SUPPLEMENT
4240020	BOLTON CCDA ANTIMICROBIC SUPPLEMENT
4240006	C.DIFFICILE ANTIMICROBIC SUPPLEMENT
4240021	CAMPYLOB.GROWTH SUPPLEMENT
4240003	CHLORAMPH.ANTIMICROBIC SUPPLEMENT
4240080	CHROMART CRE SUPPLEMENT
4240082	CHROMART ESBL SUPPLEMENT
4240053	CHROMART STREPTO B SUPPLEMENT
4240018	CNA ANTIMICROBIC SUPPLEMENT
4240024	DERMATOPHYTE ANTIMICR.SUP.
4240019	GARDNERELLA ANTIMICROBIC SUPPLEMENT
90HWH25	GLOBULI ROSSI DI MONTONE 10%
4240010	HAEMOPHILUS ANTIMICROBIC SUPPLEMENT
4240035	KARMALI ANTIMICROBIC SUPPLEMENT
423210	LEGIONELLA BCYE ALPHA GROWTH SUPPLEMENT
423212	LEGIONELLA BCYE ALPHA GROWTH SUPPLEMENT w/o CYSTEINE
423215	LEGIONELLA GVPC SELECTIVE SUPPLEMENT
90HLX100	LYSED HORSE BLOOD - 100 ml
4240026	MUG SUPPLEMENT (10X50MG)
4240027	MUG TRYPTOPHAN SUPPLEMENT
4240013	SALMONELLA SELECTIVE SUPPLEMENT
90HDG25	SANGUE DEFIBRINATO DI CAVALLO
90HDG500	SANGUE DEFIBRINATO DI CAVALLO
90HDX100	SANGUE DEFIBRINATO DI CAVALLO
90HDX50	SANGUE DEFIBRINATO DI CAVALLO
90HDG1000	SANGUE DEFIBRINATO DI MONTONE



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90SDG25	SANGUE DEFIBRINATO DI MONTONE
90SDX100	SANGUE DEFIBRINATO DI MONTONE
90SDX50	SANGUE DEFIBRINATO DI MONTONE
90SDX500	SANGUE DEFIBRINATO DI MONTONE
90SAX100	SANGUE DI MONTONE IN SOLUZIONE DI ELSEVER
90SAX25	SANGUE DI MONTONE IN SOLUZIONE DI ELSEVER
90SAX50	SANGUE DI MONTONE IN SOLUZIONE DI ELSEVER
90HLX100	SANGUE LISATO (LACCATO) DI CAVALLO
4240016	SKIRROW ANTIMICROBIC SUPPLEMENT
4240096	UREA, 40% SOLUTION
42211601	UREA, 40% SOLUTION
4240007	VCN ANTIMICROBIC SUPPLEMENT
4240008	VCNT ANTIMICROBIC SUPPLEMENT
4240011	YERSINIA SEL.SUPPLEMENT

READY TO USE TUBES FOR MICROBIOLOGY

EDMA CLASS. 14 01 02 01 / 14 01 13 01/ 14 03 03 01

223282	TRANSFEC
551230	BRAIN HEART INFUSION BROTH
521230P	BRAIN HEART INFUSION BROTH 3 ml
554050	BRODO SIERO
553691	DERMATOPHYTE SELECTIVE MEDIUM
551524	G N BROTH HAJNA
551634	IUT MEDIUM
551560	KLIGLER IRON AGAR
554001	LOEFFLER MEDIUM
551635W	LOWENSTEIN JENSEN MEDIUM W/O GLIGEROL
551635	LOWENSTEIN-JENSEN MEDIUM
551636	LYSINE IRON AGAR
551743	MULLER KAUFFMANN TETRATHIONATE BROTH
551810	NUTRIENT AGAR
551815	NUTRIENT BROTH
554002	PERGOLA MEDIUM
551980	RAPPARORT VASSILIADIS BROTH
552000	SABOURAUD BROTH
552005	SABOURAUD DEXTROSE AGAR
552006	SABOURAUD DEXTROSE AGAR CAF 50
552008	SABOURAUD DEXTROSEAGAR CAF-CEX
552025	SELENITE BROTH
552137	THIOGLYCOLLATE MEDIUM
552134B	TODD HEWITT CNA BROTH
552134	TODD HEWITT BROTH
5513311	TRICHOMONAS CPLM SELECTIVE BROTH
552141	TRIPLE SUGAR IRON AGAR
552150	TRYPTIC SOY AGAR
522150P	TRYPTIC SOY AGAR, 3 ml
552155	TRYPTIC SOY BROTH
551145	TRYPTOSE AGAR
551146	TRYPTOSE BROTH
552175	UREA AGAR
552180	UREA BROTH

READY TO USE FLASKS FOR MICROBIOLOGY

EDMA CLASS. 14 01 03 01 / 14 03 03 03

5115412	HEKTOEN ENTERIC AGAR (6X100ML)
5115413	HEKTOEN ENTERIC AGAR (6X200ML)
5115822	LEGIONELLA BCYE AGAR BASE (6X 90 ML)
5115824	LEGIONELLA BCYE AGAR BASE (6X180ML)
5115823	LEGIONELLA BCYE AGAR BASE (6X225ML)
5116702	MAC CONKEY AGAR (6X100ML)
5116703	MAC CONKEY AGAR (6X200ML)
5116652	MANNITOL SALT AGAR -6X100ML
5116653	MANNITOL SALT AGAR -6X200ML



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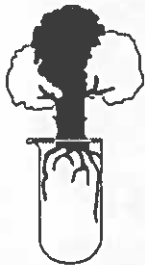
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5117432	MULLER KAUFFMAN TET.BROTH (6X100ML)
5118102	NUTRIENT AGAR (6X100ML)
5119632	PSEUDOMONAS SELECTIVE AGAR (6X100ML)
5119802	RAPPAPORT VASSILIADIS BROTH (6X100ML)
5120002	SABOURAUD BROTH (6X100ML)
5120052	SABOURAUD DEXTROSE AG.-6X100ML
5120053	SABOURAUD DEXTROSE AG.-6X200ML
5120062	SABOURAUD DEXTROSE AGAR+CAF 6X100ML
5120063	SABOURAUD DEXTROSE AGAR+CAF 6X200ML
5120252	SELENITE BROTH (6X100ML)
5120752	SS AGAR (6X100ML)
5121062	TCBS AGAR -6X100ML
5121372	THIOGLYCOLLATE MEDIUM (6X100ML)
5121502	TRYPTIC SOY AGAR (6X100ML)
5121503	TRYPTIC SOY AGAR (6X200ML)
5121552	TRYPTIC SOY BROTH -6X100ML
5121553	TRYPTIC SOY BROTH -6X200ML

READY TO USE PLATES FOR MICROBIOLOGY

EDMA CLASS. 14 01 04/ 14 03 02

541100	AZIDE BLOOD AGAR
549988	BACTEROIDES BILE AESCULIN AGAR
541014VR	BEEA-VAN (BILE ESCULIN AZIDE AGAR-VANCOMYCIN)
541180	BLOOD AGAR HORSE
541151	BLOOD AGAR SHEEP
549905	BORDETELLA SELECTIVE AGAR
541235	BRAIN HEART INFUSION AGAR
(58) 501808	BRAIN HEART INFUSION AGAR
541274	BRUCELLA AGAR HORSE
(58) 501823	BRUCELLA BLOOD AGAR +5% SANGUE DI CAVALLO
541111	CAMPYLOBACTER AGAR BLASER WANG
541111B	CAMPYLOBACTER SELECTIVE AG. SKIRROW
541283	CAMPYLOBACTER BLOOD FREE MEDIUM (KARMALI)
541519	CHOCOLATE AGAR BACITRACINE
541521	CHOCOLATE AGAR ENRICHED
548000	CHROMALBICANS AGAR
548015	CHROMART CRE
548020	CHROMART ESBL
548010	CHROMART STREPTO B
548005	CHROMOGENIC CANDIDA AGAR (CCA)
545350	CHROMOGENIC SALMONELLA AGAR
545350S	CHROMOGENIC SALMONELLA AGAR CLEAR
549810S	CHROMOGENIC URINE AGAR III
549810G	CHROMOGENIC URINE AGAR IV
541901	CLED AGAR
541308	CLOSTRIDIUM DIFFICILE SELECTIVE MEDIUM
541136	COLUMBIA BLOOD AGAR
541361	COLUMBIA CNA BLOOD AGAR
541363	COLUMBIA CNA-CV BLOOD AGAR
541369	DERMATOPHYTE SELECTIVE MEDIUM (DTM)
541370	DESOXYCHOLATE AGAR
549993	GARDNERELLA SELECTIVE AGAR
549901	HAEMOPHILUS TEST MEDIUM
541541	HEKTOEN ENTERIC AGAR
549994	HERELLEA AGAR
(58) 501815	HERELLEA AGAR
549945	LEGIONELLA AGAR
549943	LEGIONELLA AGAR w/o CYSTEINE
549995	LEGIONELLA SELECTIVE AGAR (GVPC)
541595	LEVINE EMB AGAR
(58) 501813	E.M.B. (LEVINE) AGAR
541670	MAC CONKEY AGAR
541672	MAC CONKEY AGAR MUG



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(58) 501817	MAC CONKEY MUG
541669S	MAC CONKEY SORBITOL AGAR
541669	MAC CONKEY SORBITOL MUG AGAR
541665	MANNITOL SALT AGAR
541522	MODIFIED THAYER MARTIN (MTM) AGAR
501740P	MUELLER HINTON AGAR II
(58) 501817	MUELLER HINTON AGAR Ø 150
549860	MUELLER HINTON AGAR + 2% NaCl
541743	MUELLER HINTON AGAR BLOOD SHEEP
541740F	MHA- F
541740	MUELLER HINTON AGAR II
501743P	MUELLER HINTON AGAR BLOOD SHEEP
541742	MUELLER HINTON CHOCOLATE AGAR
541810	NUTRIENT AGAR
549510	OXACILLIN SCREEN AGAR
541963	PSEUDOMONAS SELECTIVE AGAR
541971	PURPLE LACTOSE AGAR
501971P	PURPLE LACTOSE AGAR
541985	ROGOSA BIOS AGAR
(58) 501820	ROGOSA AGAR
54RPMI90	RPMI AGAR 90 mm
54RPMI15	RPMI AGAR 150 mm
542005	SABOURAUD DEXTROSE AGAR
542006	SABOURAUD DEXTROSE AGAR + CAF
542008	SABOURAUD DEXTROSE AGAR + CAF + CEX
542009	SABOURAUD DEXTROSE AGAR + CAF + GENTAMICIN
549989	SCHAEGLER BLOOD AGAR
549990	SCHAEGLER SELECTIVE BLOOD AGAR
549907	SCHAEGLER SELECTIVE CNA BLOOD AGAR
549998	SERUM TELLURITE AGAR
542046	SLANETZ BARTLEY AGAR
542075	SS AGAR
546550	STRONGYLOIDES STERCORALIS AGAR
549850	SUPPLEMENTED BRUCELLA AGAR
542106	TCBS KOBAYASHI AGAR
(58) 501825	TCBS CHOLERA AGAR
542150	TRYPTIC SOY AGAR
542181	UREAPLASMA DIFFERENTIAL AGAR A7
549520	VANCOMYCIN SCREEN AGAR
542200	WURTZ AGAR
(58) 501826	WURTZ AGAR
542206	XLD AGAR
549997	YERSINIA SELECTIVE AGAR
491001	BIOSECTOR 1 HEKTOEN ENTERIC AGAR / SS AGAR
(48) 501830	HEKTOEN ENTERIC AGAR / SS AGAR
491003	BIOSECTOR 3 BLOOD AGAR SHEEP / MAC CONKEY AGAR MUG
(48) 502247	BLOOD AGAR (5% SANGUE MONTONE) / MAC CONKEY AGAR + MUG
491004	BIOSECTOR 4 BLOOD AGAR / MAC CONKEY AG. MUG / SLANETZ MOD. AGAR
(48) 501832	BLOOD AGAR (5% SANGUE MONTONE) / MAC CONKEY AGAR + MUG / SLANETZ-BARTLEY TTC AGAR
491006	BIOSECTOR 6 COLUMBIA CAN BLOOD AGAR / BLOOD AGAR SHEEP
491010	BIOSECTOR 10 MOD. THAYER MARTIN AG. / CHOC. AG. ENR. / GARD. SEL. AG.
(48) 501833	THAYER MARTIN AGAR-G.VAGINALIS SEL. AG.-CHOCOLATE (VITOX) AGAR
491013	BIOSECTOR 13 DERMATOPHYTE TEST MEDIUM / SABOURAUD DEXT. AGAR CAF
(48) 501829	DERMASEL SELECTIVE AGAR / SABOURAUD DEXT. AGAR + CLORAMFENICOL
491025	BIOSECTOR 25 MOD. THAYER MARTIN AGAR / GARD. SEL. AGAR
491032	BIOSECTOR 32 XLD AGAR / SS AGAR
491037	BIOSECTOR 37 MAC CONKEY AGAR / SS AGAR
491054	BIOSECTOR 54 BLOOD AGAR SHEEP / MAC CONKEY AGAR
491070	CETRIMIDE AGAR / MAC CONKEY AGAR / BP AGAR
495350	BIOSECTOR CHROMOGENIC SALMONELLA AGAR / HEKTOEN ENTERIC AGAR
495351	BIOSECTOR CHROMOGENIC SALMONELLA AGAR / XLD AGAR
491042C	BIOSECTOR 42C MOD. THAYER MARTIN AGAR / CHOCOLATE. AG. ENR. / CHROMALBICANS AGAR

PRODUCTS FOR MICROBIAL IDENTIFICATION



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EDMA CLASS 14 02 02 / 14 03 04

429936	COAGULASE PLASMA EDTA
429937	COAGULASE PLASMA EDTA
429938	COAGULASE PLASMA EDTA
19171000	KOVACS' REAGENT
19171001	KOVACS' REAGENT
191500	MUCAP TEST
19171002	OXIBIOSWAB
191040ST	OXIDASE TEST STRIPS

IVD OTHER

EDMA CLASS 14 90 / 14 01 13 01

224001	SPUTAFLUID
225020	A.L.L. SOLUTION
225040	PHOSPHATE BUFFER 0,067M pH 6,8
2203454	DIGESTION REAGENT
225000	A.L.L. DIGESTION NEUTRALISATION KIT