

## DECLARATION OF CONFORMITY

(According to Regulation (EU) 2017/746, ARTICLE 17, ANNEX IV)

The undersigned manufacturer of In Vitro Diagnostic Medical Devices, Class A, hereby declares that:

For the In Vitro Diagnostic Medical Devices covered by this Declaration of Conformity, the requirements defined in Regulation (EU) 2017/746 are met.

This Declaration of Conformity is issued under my responsibility and contains, at a minimum, the information specified in Annex IV.

### MANUFACTURER DETAILS

**Manufacturer:** G. PAPANIKOLAOU & CO. Ltd.

**Trade Name:** 

**Address:** Potamou 5, BIO PA KERATEAS – ATTICA, ZIP Code 19001

**Contact Information:** Phone: +30 2299 0 66113. Fax: +30 2299 0 66112. Email: bioprep1@otenet.gr

**SRN:**

**Quality Management Standard:** ISO 13485/2016

### MEDICAL DEVICE DETAILS

**Risk Category:** A

**Classification Rule:** 5

(According to the classification rules in Annex VIII of the new Regulation (EU) 2017/746)

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
010224	AEROMONAS BLOOD AGAR	Selective isolation of Aeromonas	5212037714010401WF
010003	ANAEROBE C.N.A. BLOOD AGAR	Selective isolation of anaerobic gram-positive cocci	5212037714010401WF
010220	ANAEROBE BLOOD AGAR W/KANAMYCIN & VANCOMYCIN	Selective isolation of gram-negative anaerobic bacteria	5212037714010401WF
010101	ANAEROBE BLOOD AGAR W/VANCOMYCIN & NEOMYCIN	Isolation and identification of <i>Bacteroides fragilis</i>	5212037714010401WF
010005	BACTEROIDES BILE ESCULINE AGAR	Isolation and identification of <i>Bacteroides fragilis</i>	5212037714010401WF
010274	BILE ESCULINE AZIDE AGAR W/VANCOMYCIN	Isolation of vancomycin-resistant <i>E. faecalis</i> .	5212037714010401WF
010246	BORDET SELECTIVE AGAR	For the selective cultivation of <i>Bordetella</i> species.	5212037714010401WF
010248	BHI SELECTIVE AGAR W/ HORSE BLOOD	For the isolation of fastidious bacteria.	5212037714010401WF

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
010016	BRILLIANT GREEN AGAR	For the selective isolation of <i>Salmonella</i> species	5212037714010401WF
010020	CAMPYLOBACTER AGAR (SELECTIVE MEDIUM)	For the selective cultivation of <i>Campylobacter</i> spp in feces	5212037714010401WF
010021	CAMPYLOBACTER BLOOD FREE AGAR (mCCD)	Selective cultivation of <i>Campylobacter</i> spp from clinical samples	5212037714010401WF
010636	CAMPYLOBACTER SELECTIVE AGAR (SKIRROW)	Selective cultivation of <i>Campylobacter</i> spp from clinical samples.	5212037714010401WF
020634	CAMPYLOBACTER BLOOD FREE AGAR (mCCD) – CAMPYLOBACTER BLOOD AGAR (SKIRROW) (ISO 10272)	Selective dichotomous for the isolation of <i>Campylobacter</i> spp	5212037714010401WF
010027	CHOCOLATE BACITRACIN AGAR	For the selective isolation of <i>Haemophilus influenzae</i>	5212037714010401WF
010034	CLED AGAR	For the selective cultivation of uropathogenic bacteria	5212037714010401WF
010035	CLOSTRIDIUM DIFFICILE AGAR CCEY (Brazier's)	For the selective cultivation of <i>Clostridium difficile</i>	5212037714010401WF
010251	COLUMBIA C.N.A. (Horse Blood)	For the isolation and identification of gram-positive cocci	5212037714010401WF
010371	COLUMBIA C.N.A. (Sheep Blood)	For the isolation and identification of gram-positive cocci	5212037714010401WF
20065	CONTACT PLATE MAC CONKEY AGAR (CP MC)	For the microbiological testing of gram-negative bacteria on surfaces	5212037714010401WF
010040	DESOXYCHOLATE CITRATE AGAR	For the isolation and identification of enterobacteria	5212037714010401WF
010488	DRIGALSKI LACTOSE AGAR	Cultivation and isolation of Enterobacteriaceae (urine, water & food)	5212037714010401WF
010218	EGG YOLK ANAEROBE WITH NEOMYCIN	For the selective isolation of clostridia	5212037714010401WF
010044	GARDNERELLA AGAR	For the selective isolation of <i>Gardnerella vaginalis</i>	5212037714010401WF
010047	HEKTOEN ENTERIC AGAR	For the selective cultivation of enterobacteria	5212037714010401WF
010059	K.V. LAKED BLOOD AGAR w/ Vit. K1 & Hemin	Καλλιέργεια & απομόνωση των αναερόβιων Gram(-) βακτηρίων.	5212037714010401WF
010056	LEVINE EMB AGAR	For the cultivation, isolation, and identification of Enterobacteriaceae	5212037714010401WF
010065 050065	MAC CONKEY AGAR	For the cultivation and identification of Enterobacteriaceae	5212037714010401WF
020065	MAC CONKEY AGAR (BI-PLATE)	Inhibitory medium used for the cultivation, isolation, and identification of Enterobacteriaceae. ( <i>Enterococcus</i> does not grow)	5212037714010401WF
010066 050066	MAC CONKEY AGAR No2	For the cultivation and identification of Enterobacteriaceae and <i>Enterococcus</i>	5212037714010401WF
020066	MAC CONKEY AGAR No2 (BI-PLATE)	Inhibitory medium in which, with the addition of bile salts No.2, <i>Enterococcus</i> (in addition to Enterobacteriaceae) grows. <i>Staphylococcus</i> or other gram-positive cocci do not grow	5212037714010401WF
010267 050267	MAC CONKEY AGAR Without Crystal Violet	For the identification of bacteria that ferment lactose. Gram-positive cocci also grow.	5212037714010401WF
010684	MAC CONKEY AGAR w/o Crystal Violet & w/o Sodium Chloride	For the identification of bacteria that ferment lactose. Gram-positive cocci also grow. The swarming of <i>Proteus</i> is inhibited.	5212037714010401WF

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MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
010168	MAC CONKEY SORBITOL AGAR	For the selective separation of <i>Escherichia coli</i> O157:H7	5212037714010401WF
010068 050068	MANNITOL SALT AGAR (CHAPMAN)	For the cultivation and isolation of <i>Staphylococcus</i>	5212037714010401WF
020068	MANNITOL SALT AGAR (BI-PLATE)	Saline nutrient medium for the cultivation, isolation, and identification of pathogenic <i>Staphylococcus</i>	5212037714010401WF
010388	P.E.A. BLOOD AGAR W/ Vit. K1 & Hemin	Cultivation and isolation of anaerobic gram-positive cocci	5212037714010401WF
010087	PHENYLETHYL ALCOHOL BLOOD AGAR	For the selective isolation of gram-positive cocci	5212037714010401WF
010182	SERUM TELURITE AGAR	For the isolation of strains from the genus <i>Corynebacterium</i>	5212037714010401WF
010106 050106	S.S. AGAR	Selective medium used for the isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species	5212037714010401WF
020106	S.S. AGAR (BI-PLATE)	Selective medium used for the isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species	5212037714010401WF
030157	S.S. AGAR – HEKTOEN ENTERIC AGAR - XLD AGAR	Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. / Isolation and identification of Enterobacteriaceae, specifically for <i>Shigella</i> . / Isolation of <i>Salmonella</i> and <i>Shigella</i> species from clinical samples. RECOMMENDED FOR FECAL CULTURE.	5212037714010401WF
020552	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL - MANNITOL SALT AGAR	Fungal cultivation. Contains chloramphenicol to inhibit gram-positive and gram-negative bacteria. / Cultivation, isolation, and identification of pathogenic <i>Staphylococcus</i> .	5212037714010401WF
010109	T.C.B.S. AGAR	For the selective isolation of cholera vibrio ( <i>Vibrio</i> ).	5212037714010401WF
010111 050111	THAYER MARTIN AGAR	For the selective isolation of <i>Neisseria gonorrhoeae</i> .	5212037714010401WF
010130	X.L.D. AGAR	For the isolation of <i>Salmonella</i> and <i>Shigella</i> .	5212037714010401WF
010132	YERSINIA SELECTIVE AGAR	For the isolation and identification of <i>Yersinia enterocolitica</i> .	5212037714010401WF
010002	ANAEROBE CDC BLOOD AGAR	Cultivation of anaerobic bacteria	5212037714010490X8
020133	ANAEROBE CDC – ANAEROBE C.N.A.	Cultivation of all anaerobic bacteria (CDC). / Isolation, identification of anaerobic gram-positive cocci (C.N.A.).	5212037714010490X8
030151	ANAEROBE CDC – ANAEROBE CNA – BACTEROIDES BILE ESCULINE AGAR (BBE)	Cultivation of all anaerobic bacteria (CDC). / Isolation, identification of anaerobic gram-positive cocci (C.N.A.) / Isolation, identification of <i>B. Fragilis</i> (BBE).	5212037714010490X8
020134	ANAEROBE CDC – BACTEROIDES BILE ESCULINE AGAR (BBE)	Cultivation of all anaerobic bacteria (CDC) / Isolation, identification of <i>B. Fragilis</i> (BBE).	5212037714010490X8
020224	ANAEROBE C.N.A. – BACTEROIDES BILE ESCULINE AGAR (BBE)	Isolation, identification of anaerobic gram-positive cocci (C.N.A.). / Isolation, identification of <i>B. Fragilis</i> (BBE).	5212037714010490X8
010010	BILE ESCULINE AGAR	For the identification of <i>Enterococcus</i> .	5212037714010490X8
010011 050011	BLOOD AGAR (SHEEP BLOOD)	For the cultivation of all aerobic bacteria.	5212037714010490X8
010012 050012	BLOOD AGAR (HORSE BLOOD)	For the cultivation of all aerobic bacteria.	5212037714010490X8

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
020012	BLOOD AGAR (HORSE BLOOD) (BI-PLATE)	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci.	5212037714010490X8
020136	BLOOD AGAR – CHOCOLATE AGAR	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus</i> , <i>Neisseria</i> .	5212037714010490X8
020303	BLOOD AGAR – CHOCOLATE BACITRACINE	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Isolation of <i>Haemophilus influenzae</i> .	5212037714010490X8
020137	BLOOD AGAR – MAC CONKEY AGAR	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae and Enterococcus.	5212037714010490X8
020138	BLOOD AGAR – MAC CONKEY AGAR No2	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae and Enterococcus.	5212037714010490X8
030154	BLOOD AGAR – MAC CONKEY AGAR – CHROMagar CANDIDA	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae. (Enterococcus does not grow). / Isolation and identification of Candida strains.	5212037714010490X8
030155	BLOOD AGAR – MAC CONKEY AGAR – MANNITOL SALT AGAR (CHAPMAN)	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae. / Cultivation, isolation, and identification of pathogenic <i>Staphylococcus</i> .	5212037714010490X8
030152	BLOOD AGAR – MAC CONKEY AGAR – SABOURAUD DEXT. AGAR	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae. (Enterococcus does not grow). / Fungal cultivation. Contains chloramphenicol to inhibit gram-positive and gram-negative bacteria.	5212037714010490X8
030153	BLOOD AGAR – MAC CONKEY AGAR No2 – SABOURAUD DEXT. AGAR	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of Enterobacteriaceae and Enterococcus. / Fungal cultivation. Contains chloramphenicol to inhibit gram-positive and gram-negative bacteria..	5212037714010490X8
010014	BORDET GENGOU AGAR	For the cultivation of <i>Bordetella</i> species.	5212037714010490X8
010015	BRAIN HEART INFUSION AGAR	For the cultivation of fastidious bacteria.	5212037714010490X8
010017	BRUCELLA BLOOD AGAR	For the cultivation and isolation of <i>Brucella</i> species.	5212037714010490X8
010395	BRUCELLA BLOOD AGAR W/ Vit. K1 + Hemin	General cultivation and isolation of anaerobic bacteria.	5212037714010490X8
010025 050025	CHOCOLATE AGAR (HORSE BLOOD)	Cultivation of microaerophilic bacteria ( <i>Haemophilus</i> , <i>Neisseria</i> ).	5212037714010490X8

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
020025	CHOCOLATE AGAR (HORSE BLOOD) (Bi-plate)	Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus and Neisseria</i> .	5212037714010490X8
020140	CHOCOLATE AGAR – GARDNERELLA AGAR	Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus, Neisseria</i> . / Selective isolation of <i>Gardnerella vaginalis</i> .	5212037714010490X8
020139	CHOCOLATE AGAR – SABOURAUD DEXT. AGAR	Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus, Neisseria</i> . / Fungal cultivation. Contains chloramphenicol to inhibit gram-positive and gram-negative bacteria.	5212037714010490X8
020141	CHOCOLATE AGAR – THAYER MARTIN AGAR	Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus, Neisseria</i> . / Isolation of <i>Neisseria gonorrhoeae</i> .	5212037714010490X8
030156	CHOCOLATE AGAR – THAYER MARTIN – GARDNERELLA AGAR	Cultivation of microbes with special nutritional requirements, such as <i>Haemophilus, Neisseria</i> . / Isolation of <i>Neisseria gonorrhoeae</i> / Selective isolation of <i>Gardnerella vaginalis</i> .	5212037714010490X8
030743	CHROMagar™ SALMONELLA PLUS – S.S. AGAR – CHROMagar™ Y. enterocolitica	Selective isolation and identification of <i>Salmonella</i> species. / Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. / For the detection & differentiation of <i>Yersinia enterocolitica</i> . CULTIVATION OF FECES IS RECOMMENDED.	5212037714010490X8
030121	CHROMagar ORIENTATION – MAC CONKEY AGAR No 2 - CHROMagar CANDIDA	Isolation, identification of gram-negative bacteria, gram-positive cocci ( <i>Enterococcus, E. coli, Klebsiella, Proteus</i> ). / Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> and <i>Enterococcus</i> . / Isolation and identification of <i>Candida</i> strains.	5212037714010490X8
010676	COLUMBIA C.N.A. BLOOD AGAR W/ Trimethoprim 010676	For the isolation and identification of gram-positive cocci.	5212037714010490X8
010249	COLUMBIA HORSE BLOOD AGAR	For the cultivation of all aerobic bacteria.	5212037714010490X8
020261	COLUMBIA C.N.A. W/ 6% HORSE BLOOD – MAC CONKEY AGAR	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> . ( <i>Enterococcus</i> does not grow).	5212037714010490X8
020847	COLUMBIA C.N.A. W/ 6% HORSE BLOOD – MAC CONKEY AGAR No 2	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> and <i>Enterococcus</i> .	5212037714010490X8
020527	COLUMBIA W/ 5% HORSE BLOOD – MAC CONKEY AGAR No 2	Cultivation of all aerobic bacteria and identification of hemolytic gram-positive cocci. / Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> and <i>Enterococcus</i> .	5212037714010490X8
010250	COLUMBIA SHEEP BLOOD AGAR	For the cultivation of all aerobic bacteria.	5212037714010490X8
20012	CONTACT PLATE BLOOD AGAR (HORSE BLOOD) (CP BA)	For the bacteriological control of fastidious bacteria on surfaces.	5212037714010490X8

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
20119	CONTACT PLATE TRYPTONE SOY AGAR (CP TSA)	For the bacteriological control on surfaces.	5212037714010490X8
20120	CONTACT PLATE T.S.A. W/ LT (C.P. T.S.A. W/ LT)	Contact plates for surface control with disinfectant substances.	5212037714010490X8
010041	DNASE TEST AGAR	For the identification of the pathogenic <i>staphylococcus</i> , which breaks down the material's DNA with the production of the enzyme DNase.	5212037714010490X8
010392	Non-Nutrient Agar (Page Amoeba Saline) (NN Agar)	A non-nutrient medium for the cultivation of <i>Acanthamoeba</i> .	5212037714010490X8
010083	NUTRIENT AGAR	A nutrient medium on which all common microbes grow.	5212037714010490X8
020276	NUTRIENT AGAR – MAC CONKEY AGAR No2	Cultivation of all aerobic bacteria. / Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> . (Enterococcus grows).	5212037714010490X8
010119 050119	TRYPTONE SOY AGAR	Used for the cultivation of microbes with both special and non-special nutritional requirements.	5212037714010490X8
010240 050240	TRYPTONE SOY AGAR W/ 5% HORSE BLOOD	For the cultivation of all aerobic bacteria.	5212037714010490X8
010258 050258	TRYPTONE SOY AGAR W/ 5% SHEEP BLOOD	For the cultivation of all aerobic bacteria.	5212037714010490X8
020226	S.S. AGAR – HEKTOEN ENTERIC AGAR	Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. / Isolation and identification of <i>Enterobacteriaceae</i> , specifically for <i>Shigella</i> . RECOMMENDED FOR FECAL CULTURE.	5212037714010490X8
020558	S.S. AGAR – MAC CONKEY AGAR	Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. / Isolation and identification of <i>Enterobacteriaceae</i> .	5212037714010490X8
020679	S.S. AGAR – MAC CONKEY AGAR No2	Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. Cultivation, isolation, and identification of <i>Enterobacteriaceae</i> . ( <i>Enterococcus</i> does not grow).	5212037714010490X8
010455 050455	CHROMagar™ Acinetobacter	For the isolation and differentiation of <i>Acinetobacter</i> .	5212037714010402WH
010673 050673	CHROMagar™ C. Difficile	For the chromatic differentiation of <i>Clostridium difficile</i> .	5212037714010402WH
010692	CHROMagar™ Campylobacter	For the detection and differentiation of <i>Campylobacter spp.</i>	5212037714010402WH
010028 050028	CHROMagar™ CANDIDA	For the chromatic differentiation & isolation of <i>Candida spp.</i>	5212037714030202WV
20028	CONTACT PLATE CHROMagar™ CANDIDA	Contact plates for the isolation, cultivation, and identification of fungi from the genus <i>Candida</i> .	5212037714030202WV
010855 050855	CHROMagar™ CANDIDA Plus	A new chromogenic material that detects and differentiates <i>Candida auris</i> from other <i>Candida</i> species.	5212037714030202WV
010482 050482	CHROMagar™ CTX	Detection of Gram (-) bacteria with CTX-M-ESBL resistance.	5212037714010404WM
010361 050361	CHROMagar™ ENTEROCOCCUS	For the chromatic differentiation and isolation of <i>Enterococcus spp.</i>	5212037714010402WH
010413 050413	CHROMagar™ ESBL	Detection of Gram (-) bacteria with ESBL resistance.	5212037714010404WM

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
010032 050032	CHROMagar™ E. COLI O157	For the chromatic differentiation & isolation of E. Coli O157.	5212037714010402WH
010385 050385	CHROMagar™ KPC	Detection of Gram (-) bacteria with KPC resistance.	5212037714010404WM
020857	CHROMagar™ mSuperCARBA™	For the detection of Gram (-) bacteria with reduced sensitivity to most carbapenem agents.	5212037714010404WM
010710 050710	CHROMagar™ VRE – CHROMagar™ mSuperCARBA™	Detection of Vancomycin Resistant <i>Enterococcus</i> . / For the detection of Gram (-) bacteria with reduced sensitivity to most carbapenem agents.	5212037714010404WM
010123 050123	CHROMagar™ LISTERIA	For the isolation and identification of <i>Listeria spp.</i>	5212037714010402WH
010518 050518	CHROMagar™ Malassezia	For the chromatic differentiation of <i>Malassezia fungi</i> .	5212037714030202WV
010346 050346	CHROMagar™ MRSA	Detection of MRSA ( <i>S. aureus</i> ).	5212037714010404WM
010030 050030	CHROMagar™ ORIENTATION	For the chromatic differentiation of pathogens in urine.	5212037714010402WH
010687 050687	CHROMagar™ PSEUDOMONAS Plus	For the isolation and identification of <i>Pseudomonas aeruginosa</i> .	5212037714010402WH
020672	CHROMagar™ PSEUDOMONAS / CHROMagar™ S. aureus	Selective isolation & identification of <i>Pseudomonas</i> . / Selective isolation and identification of <i>Staphylococcus</i> .	5212037714010402WH
010315 050315	CHROMagar™ SALMONELLA PLUS	For the chromatic differentiation of <i>Salmonella spp.</i>	5212037714010402WH
010031 050031	CHROMagar™ S. Aureus	For the chromatic differentiation of <i>Staphylococcus aureus</i> .	5212037714010402WH
010824 050824	CHROMagar™ SERRATIA	For the chromatic differentiation of <i>Serratia marcescens</i> .	5212037714010402WH
010753 050753	CHROMagar™ Strep A	For the chromatic differentiation of <i>Streptococcus pyogenes</i> (GAS).	5212037714010402WH
010362 050362	CHROMagar™ Strep B	For the chromatic differentiation of <i>Streptococcus agalactiae</i> (GBS).	5212037714010402WH
010360 050360	CHROMagar™ VRE	Detection of Vancomycin Resistant <i>Enterococcus</i> .	5212037714010404WM
010363 050363	CHROMagar™ VIBRIO	For the chromatic differentiation and isolation of <i>Vibrio spp.</i>	5212037714010402WH
010624 050624	CHROMagar™ Y. Enterocolitica	For the detection & differentiation of <i>Yersinia enterocolitica</i> .	5212037714010402WH
020709	CHROMagar™ Y. enterocolitica – CHROMagar O157	Detection & differentiation of <i>Yersinia enterocolitica</i> . / Isolation and identification of <i>E. coli</i> O157.	5212037714010402WH
20455	CONTACT PLATE CHROMagar™ Acinetobacter (CP C. ACIN)	For the bacteriological control of <i>Acinetobacter</i> on surfaces.	5212037714010402WH
20029	CONTACT PLATE CHROMagar™ ECC	The Contact Plate CHROMagar™ ECC is a special contact plate used for the detection and identification of <i>E. coli</i> & Coliforms.	5212037714010402WH
20123	CONTACT PLATE CHROMagar™ LISTERIA	Contact plates for the isolation and identification of <i>Listeria spp.</i>	5212037714010402WH
20687	CONTACT PLATE CHROMagar™ PSEUDOMONAS Plus	Contact plates for the isolation and identification of <i>S. aureus</i> .	5212037714010402WH

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
20031	CONTACT PLATE CHROMagar™ S. aureus	Contact plates for the isolation and identification of <i>S. aureus</i> .	5212037714010402WH
20315	CONTACT PLATE CHROMagar™ SALMONELLA PLUS	The Contact Plate CHROMagar™ SALMONELLA PLUS is a special contact plate used for the selective separation of <i>Salmonella spp.</i>	5212037714010402WH
010092 050092	RAMBACH AGAR	For the selective identification of <i>Salmonella spp.</i>	5212037714010402WH
010039	DERMATOPHYTE TEST AGAR	For the cultivation and isolation of pathogenic fungi.	5212037714030201WT
010098 050098	SABOURAUD DEXTROSE AGAR W/ CHLORAMPHENICOL	Nutrient medium specifically enriched for the cultivation of fungi. Contains chloramphenicol, making it quite selective against gram(-) and gram(+) microorganisms.	5212037714030201WT
010099 050099	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL & ACTIDIONE	Actidione inhibits the growth of saprophytic fungi for the isolation of pathogenic fungi.	5212037714030201WT
010239 050239	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL & GENTAMICIN	For the cultivation of fungi. Contains chloramphenicol and gentamicin against gram(-) and gram(+) microorganisms.	5212037714030201WT
020635	SABOURAUD ACTIDIONE – SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL	Cultivation and isolation of pathogenic fungi. / Cultivation of fungi. Contains chloramphenicol for the inhibition of gram(+) and gram(-) bacteria.	5212037714030201WT
020256	SABOURAUD ACTIDIONE – DERTMATOPHITE TEST AGAR	Cultivation of fungi. Contains chloramphenicol for the inhibition of gram(+) and gram(-) bacteria. / Cultivation and isolation of pathogenic fungi.	5212037714030201WT
010292 050292	SABOURAUD DEXTROSE AGAR	Nutrient medium specifically enriched for the cultivation of fungi.	5212037714030201WT
20098	CONTACT PLATE SABOURAUD DEXTROSE AGAR W/ CHLORAMPHENICOL	For the bacteriological control of fungi on surfaces.	5212037714030201WT
060010	BILE ESCULINE AGAR	For the identification of <i>Enterococcus</i> .	5212037714010301WA
060013	BLOOD AGAR BASE	Nutrient base for the preparation of blood agar.	5212037714010301WA
060016	BRILLIANT GREEN AGAR	For the selective isolation of <i>Salmonella species</i> .	5212037714010301WA
060026	CHOCOLATE AGAR W/ POLIENRICHMENT SUPPLEMENT	Cultivation of microaerophilic bacteria ( <i>Haemophilus, Neisseria</i> ).	5212037714010301WA
040022	CAMPYLOBACTER BROTH PRESTON	For the enrichment of <i>Campylobacter spp.</i>	5212037714010301WA
040404	CAMPYLOBACTER ENRICHMENT BROTH (Bolton)	For the enrichment of <i>Campylobacter spp.</i>	5212037714010301WA
060040	DESOXYCHOLATE CITRATE AGAR	For the isolation and identification of enterobacteria.	5212037714010301WA
060047	HEKTOEN ENTERIC AGAR	For the selective cultivation of enterobacteria.	5212037714010301WA
060065	MAC CONKEY AGAR	For the cultivation and identification of enterobacteria.	5212037714010301WA
060066	MAC CONKEY AGAR No2	For the cultivation and identification of enterobacteria and <i>Enterococcus</i> .	5212037714010301WA
060267	MAC CONKEY AGAR Without Crystal Violet	For the identification of bacteria that ferment lactose. Gram(+) cocci also grow.	5212037714010301WA

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MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
060067	MAC CONKEY BROTH	For the identification of enterobacteria that ferment lactose.	5212037714010301WA
060068	MANNITOL SALT AGAR (CHAPMAN)	For the cultivation and isolation of <i>Staphylococcus</i> .	5212037714010301WA
060075	MUELLER HINTON AGAR	Used for the antibiotic sensitivity testing of microorganisms via the diffusion method.	5212037714010301WA
060083	NUTRIENT AGAR	A nutrient medium in which all common microorganisms grow.	5212037714010301WA
060084	NUTRIENT BROTH	For the cultivation of aerobic bacteria.	5212037714010301WA
060106	S.S. AGAR	Selective nutrient medium used for the isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species.	5212037714010301WA
060102	SELENITE BROTH	For the selective isolation of <i>Salmonella</i> species.	5212037714010301WA
060119	TRYPTONE SOY AGAR	Used for the cultivation of microorganisms with both special and non-special nutritional requirements.	5212037714010301WA
060121	TRYPTONE SOY BROTH	General-purpose broth for the growth of fastidious microorganisms.	5212037714010301WA
060130	X.L.D. AGAR	For the cultivation and isolation of <i>Salmonella</i> and <i>Shigella</i> .	5212037714010301WA
060079	MUELLER HINTON BROTH	For the preparation of microbial suspensions.	5212037714010302WC
060112	THIOGLYCOLATE MEDIUM	For the growth of aerobic and anaerobic bacteria.	5212037714010302WC
070039	DERMATOPHYTE TEST AGAR	For the cultivation and isolation of pathogenic fungi.	5212037714030301WY
060039	DERMATOPHYTE TEST AGAR	For the cultivation and isolation of pathogenic fungi.	5212037714030303X4
060098	SABOURAUD DEXTROSE AGAR W/ CHLORAMPHENICOL	Nutrient medium is specifically enriched for the cultivation of fungi. Contains chloramphenicol, making it quite selective against gram(-) and gram(+) microorganisms.	5212037714030303X4
070098	SABOURAUD DEXTROSE AGAR W/ CHLORAMPHENICOL	Nutrient medium specifically enriched for the cultivation of fungi. Contains chloramphenicol, making it quite selective against gram(-) and gram(+) microorganisms.	5212037714030301WY
060099	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL & ACTIDIONE	Actidione inhibits the growth of saprophytic fungi for the isolation of pathogenic fungi.	5212037714030303X4
070292	SABOURAUD DEXTROSE AGAR	Nutrient medium specifically enriched for the cultivation of fungi.	5212037714030301WY
070099	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL & ACTIDIONE	Actidione inhibits the growth of saprophytic fungi for the isolation of pathogenic fungi.	5212037714030301WY
070239	SABOURAUD DEXT. AGAR W/ CHLORAMPHENICOL & GENTAMICIN	For the cultivation of fungi. Contains chloramphenicol and gentamicin against gram(-) and gram(+) microorganisms.	5212037714030301WY
070605	SABOURAUD DEXTROSE BROTH	Cultivation of yeasts & molds.	5212037714030301WY
010424	YEAST EXTRACT DEXTROSE CHLORAMPHENICOL AGAR	A medium for counting yeasts and molds in milk and other dairy products.	5212037714030201WT
070042	BRAIN HEART INFUSION BROTH	Broth for the cultivation of fastidious bacteria.	5212037714010201W5

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MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
080022	CAMPYLOBACTER BROTH PRESTON	For the enrichment of <i>Campylobacter spp.</i>	5212037714010201W5
080404	CAMPYLOBACTER ENRICHMENT BROTH (Bolton)	For the enrichment of <i>Campylobacter spp.</i>	5212037714010201W5
070037	COOKED MEAT MEDIUM	Cultivation of anaerobic pathogenic clostridia.	5212037714010201W5
080045	GLUCOSE BROTH	Identifying broth for glucose fermentation test.	5212037714010201W5
070495	G.N. HAJNA BROTH	For the cultivation and isolation of Gram (-) bacteria.	5212037714010201W5
080048	INDOLE BROTH	Identifying broth for indole production test.	5212037714010201W5
080061	LYSINE DECARBOXYLASE BROTH	For the identification of bacteria that break down lysine.	5212037714010201W5
080067 070067	MAC CONKEY BROTH	For the identification of enterobacteria that break down lactose.	5212037714010201W5
080074	MR – VP MEDIUM	For the methyl red reaction and V.P. test.	5212037714010201W5
070079 080079	MUELLER HINTON BROTH	For the preparation of microbial suspensions.	5212037714010201W5
070084	NUTRIENT BROTH	For testing phenylalanine breakdown.	5212037714010201W5
070093	RAPPAPORT VASILADIS BROTH	For the enrichment and isolation of <i>Salmonella</i> .	5212037714010201W5
070102 380102	SELENITE BROTH	For the selective isolation of <i>Salmonella</i> species.	5212037714010201W5
110185	STOCK CULTURE BROTH	For the preservation of standard microbial strains (at -80 °C).	5212037714010201W5
070112	THIOGLYCOLATE MEDIUM (Brewer)	For the cultivation of aerobic and anaerobic bacteria.	5212037714010201W5
070113	THIOGLYCOLATE W/ VIT. K1 + HEMIN	For the cultivation of anaerobic bacteria.	5212037714010201W5
070114	THIOGLYCOLATE W/ RESAZURIN (USP)	For the cultivation of aerobic and anaerobic bacteria.	5212037714010201W5
080115	TODD – HEWITT BROTH	Nutrient broth for the cultivation of <i>Streptococcus</i> .	5212037714010201W5
380516	TODD – HEWITT BROTH C.N.A.	For the isolation of Group B <i>Streptococcal</i> (GBS).	5212037714010201W5
080117	TRICHOMONAS BROTH	For the cultivation and maintenance of <i>Trichomonas vaginalis</i> .	5212037714010201W5
070121	TRYPTONE SOY BROTH (USP)	General-purpose broth for the cultivation of demanding microorganisms.	5212037714010201W5
080125	UREA BROTH	For testing urea breakdown.	5212037714010201W5
080183	UREA – INDOLE BROTH	For differentiating bacteria in urea and indole.	5212037714010201W5
080010	BILE ESCULINE AGAR	For the identification of <i>Enterococcus</i> .	5212037714010290WW
070015	BRAIN HEART INFUSION AGAR	For the cultivation of demanding bacteria.	5212037714010290WW
070050 080050	KLIGLER IRON AGAR	For detecting the production of H <sub>2</sub> S, glucose, gas and lactose.	5212037714010290WW
070060	LOWENSTEIN – JENSEN MEDIUM	For the cultivation of mycobacteria.	5212037714010290WW
070065	MAC CONKEY AGAR	For the cultivation and identification of enterobacteria.	5212037714010290WW
070066	MAC CONKEY AGAR No2	For the cultivation and identification of enterobacteria and <i>Enterococcus</i> .	5212037714010290WW
080174	MOTILITY TEST MEDIUM W/ TTC	For testing bacterial motility.	5212037714010290WW

## Production of Microbiological Reagents

MANUFACTURER CODE	PRODUCT NAME	INTENDED USE	BASIC UDI-DI
070083	NUTRIENT AGAR	Nutrient medium for the growth of all common microorganisms.	5212037714010290WW
080086	PHENYLALANINE AGAR (PPA)	For testing phenylalanine breakdown.	5212037714010290WW
080104	SIMMONS CITRATE AGAR	For testing the use of citrate as an energy source.	5212037714010290WW
080118 070118	TRIPLE SUGAR IRON AGAR	For testing H <sub>2</sub> S production, glucose, gas, lactose & sucrose.	5212037714010290WW
080124	UREA AGAR (CHRISTENSEN MEDIUM)	For differentiating bacteria that break down urea.	5212037714010290WW
010203 090203	H.T.M. (HAEMOPHILUS TEST MEDIUM)	For antibiotic sensitivity testing of Haemophilus.	521203771414010403SE
010075 090075 120075	MUELLER HINTON AGAR	Used for antibiotic sensitivity testing of microorganisms through diffusion method.	521203771414010403SE
010076 090076	MUELLER HINTON W/ 5% HORSE BLOOD	M.H. with 5% horse blood is used for antibiotic sensitivity testing of beta-hemolytic streptococcus.	521203771414010403SE
010704	MUELLER HINTON W/ 5% HORSE BLOOD + 20mg/L β-NAD (MH-F)	For studying antimicrobial sensitivity of Pneumococcus and other <i>Streptococcus</i> , <i>Haemophilus</i> , and <i>Moraxella</i> .	521203771414010403SE
090704	MUELLER HINTON W/ 5% HORSE BLOOD + 20mg/L β-NAD (MH-F)	For studying antimicrobial sensitivity of <i>Pneumococcus</i> and other <i>Streptococcus</i> , <i>Haemophilus</i> , and <i>Moraxella</i> .	521203771414010403SE
010078 090078	MUELLER HINTON W/ 5% NaCl	For antibiotic sensitivity testing of <i>S. aureus</i> .	521203771414010403SE
010200	MUELLER HINTON AGAR W/ OXACILLIN + NaCl	For antibiotic sensitivity testing of MRSA <i>Staphylococcus</i> .	521203771414010403SE
010293 090293 120293	RPMI GLUCOSE AGAR	For antifungal sensitivity testing using the E test.	521203771414010403SE
010383 090383 120383	MUELLER HINTON W/ 5% SHEEP BLOOD	M.H. with 5% sheep blood is used for antibiotic sensitivity testing of beta-hemolytic streptococcus.	521203771414010403SE
100331	MYCOTEST AGAR	For the cultivation, identification, and counting of urogenital mycoplasmas <i>Mycoplasma hominis</i> & <i>Ureaplasma urealyticum</i> .	5212037714020207WU
100339	MYCOPLASMA HUF	For laboratory diagnosis of urogenital mycoplasmas <i>M. hominis</i> , <i>U. urealyticum</i> , & <i>M. fermentans</i> .	5212037714020207WU
100332	MycoTest ST	For testing sensitivity of <i>M. hominis</i> & <i>U. urealyticum</i> to four antibiotics.	5212037714020207WU
100081	MYCOTEST	For identification and semi-quantitative determination of <i>M. hominis</i> (Mh) and <i>U. urealyticum</i> (Uu).	5212037714020207WU
050080	MYCOPLASMA AGAR – A7	For the cultivation of <i>U. urealyticum</i> and <i>M. hominis</i> .	5212037714020207WU
080096 380096	MYCOPLASMA BROTH U-A (M. U-A)	For detection, transfer, and preservation of urogenital mycoplasmas.	5212037714020207WU
020211	BLOOD AGAR – CHROMagar™ ORIENTATION	Cultivation of all aerobic bacteria and identification of hemolytic gram(+) cocci. / Isolation and identification of gram(-)	521203771414010405SJ

## Production of Microbiological Reagents

		bacteria, gram(+) cocci ( <i>Enterococcus</i> , <i>E. coli</i> , <i>Klebsiella</i> , <i>Proteus</i> ).	
020731	CHROMagar™ Campylobacter – CAMPYLOBACTER AGAR (SELECT. MEDIUM)	For detection and differentiation of <i>Campylobacter spp.</i> - For selective cultivation of <i>Campylobacter spp.</i>	521203771414010405SJ
020266	CHROMagar™ ORIENTATION – COLUMBIA C.N.A. BLOOD AGAR	Isolation and identification of gram(-) bacteria, gram(+) cocci ( <i>Enterococcus</i> , <i>E. coli</i> , <i>Klebsiella</i> , <i>Proteus</i> ). / Isolation and identification of gram(+) cocci.	521203771414010405SJ
020142	CHROMagar™ ORIENTATION – MAC CONKEY AGAR	Isolation and identification of gram(-) bacteria, gram(+) cocci ( <i>Enterococcus</i> , <i>E. coli</i> , <i>Klebsiella</i> , <i>Proteus</i> ). / Cultivation, isolation, and identification of Enterobacteriaceae. ( <i>Enterococcus</i> does not grow). RECOMMENDED FOR URINE CULTURE.	521203771414010405SJ
020523	CHROMagar™ SALMONELLA PLUS – HEKTOEN ENTERIC AGAR	Selective isolation and identification of <i>Salmonella spp.</i> / Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. RECOMMENDED FOR FECAL CULTURE.	521203771414010405SJ
020316	CHROMagar™ SALMONELLA PLUS – S.S. AGAR	Selective isolation and identification of <i>Salmonella spp.</i> / Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. RECOMMENDED FOR FECAL CULTURE.	521203771414010405SJ
020856	CHROMagar™ SALMONELLA PLUS – MAC CONKEY AGAR	Selective dual-purpose medium for the selective isolation and chromogenic identification of <i>Salmonella spp.</i> (CHROMagar™ SALMONELLA PLUS). Also used for the isolation and identification of <i>Enterobacteriaceae</i> (MAC CONKEY AGAR).	521203771414010405SJ
020382	CHROMagar™ SALMONELLA PLUS – XLD AGAR	Selective dual-purpose medium for the isolation of <i>Salmonella</i> .	521203771414010405SJ
020756	CHROMagar™ Strep A – COLUMBIA C.N.A. BLOOD AGAR	Identification of Group A <i>Streptococci</i> ( <i>Streptococcus pyogenes</i> ) in throat samples. / Isolation and identification of gram(+) cocci.	521203771414010405SJ
020640	S.S. AGAR – RAMBACH AGAR	Isolation and identification of <i>Salmonella</i> and <i>Shigella</i> species. / For the selective isolation and identification of <i>Salmonella spp.</i>	521203771414010405SJ
380835	VCM Transport Medium	VCM (Virus Transport Medium) is used as a preservative for transporting clinical samples containing viruses, <i>Chlamydia</i> , and <i>Mycoplasmas</i> ( <i>Mycoplasma hominis</i> & <i>Ureaplasma urealyticum</i> ) from the collection site to the testing laboratory. It also inhibits or slows down the growth of bacteria or fungi in the sample.	521203771414010220S4
380830 380831	Virus Transport Medium (GLYE)	Virus Transport Medium (GLYE) is used as a preservative for maintaining the viability of viruses from the collection site to the testing laboratory.	521203771414010220S4
380825 380826	Virus Transport Medium (RT)	Virus Transport Medium (RT) is used as a preservative for maintaining the viability of viruses from the collection site to the testing laboratory.	521203771414010220S4



#### Production of Microbiological Reagents

With this declaration, I state that:

The In Vitro Diagnostic Medical Devices covered by this declaration meet the specifications included in the technical file of the products, which contains the information specified in Annexes II and III of Regulation (EU) 2017/746, as applicable, and is updated as required by the Regulation.

The In Vitro Diagnostic Medical Devices covered by this declaration comply with the requirements of Regulation (EU) 2017/746 and with the requirements of any other Union legislation applicable to the technological products covered by this declaration. The EU Declaration of Conformity will be updated on an ongoing basis.

The In Vitro Diagnostic Medical Devices covered by this declaration meet the general safety and performance requirements defined in Annex I of Regulation (EU) 2017/746 and apply to them, in accordance with their intended use as declared in this document, according to the classification rules of Annex VIII of Regulation (EU) 2017/746.

#### THE DECLARANT

On behalf of the company G. PAPANIKOLAOU & CO. Ltd.

Keratea, 18/01/2024

Bioprepere  
G. PAPANIKOLAOU & Co. LP  
MICROBIOLOGICAL REAGENTS PRODUCTION  
POTAMOUS - INDUSTRIAL AREA - KERATEA - GREECE PC 19001  
VAT: EL098941030 - KE FO.D.E. ATTIKIS  
TEL +30 22930 65113 - E-mail: bioprep1@otenet.gr

Georgios Papanikolaou  
General Manager