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## EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various	<b>MAST DISCS</b> <sup>®</sup> AST – paper antimicrobial susceptibility test (AST) discs products	Self certification Annex III excluding section 6	1402050200 (Code registered - 02/12/2002)  GMDN code - 17005

Standards applied: EN ISO 13485:2012, ISO 9001:2008, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by ..... Date: 30 January 2019

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 01 December 2022





European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD  
 EC DECLARATION OF CONFORMITY- Self-Certification (Annex III excluding section 6) – General IVD  
 Product Names: MASTDISCS – antimicrobial susceptibility discs in vials and cartridges

Annex – list of Mast AST Discs products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	AK30C	Amikacin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
2	A2C	Amoxicillin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
3	A10C	Amoxicillin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
4	A25C	Amoxicillin 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
5	AMB20C	Amphotericin B 20ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
6	AP2C	Ampicillin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
7	AP10C	Ampicillin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
8	AP25C	Ampicillin 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
9	SAM20C	Ampicillin10ug/Sulbactam10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
10	AUG3C	Amoxicillin/clavulanic acid 2-1	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
11	AUG30C	Amoxicillin/clavulanic acid 20-10	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
12	ATH15C	Azithromycin 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
13	ATM30C	Aztreonam 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
14	BA10C	Bacitracin 10 units	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
15	PY100C	Carbenicillin 100ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
16	CFC30C	Cefaclor 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
17	CFB30C	Ceftibuten 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
18	CMD30C	Cefamandole 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Certificate No: 932114



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
19	CDX30C	Cefadroxil 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
20	CPM30C	Cefepime 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
21	CFM5C	Cefixime 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	CPZ30C	Cefoperazone 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	CPZ75C	Cefoperazone 75ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CTX5C	Cefotaxime 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CTX30C	Cefotaxime 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	FOX10C	Cefoxitin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	FOX30C	Cefoxitin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CPD10C	Cefpodoxime 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CPT5C	Ceftaroline 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CPT30C	Ceftaroline 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CZA14C	Ceftazidime/avibactam 10-4	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	CZA50C	Ceftazidime/avibactam 30-20	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	CAZ10C	Ceftazidime 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	CAZ30C	Ceftazidime 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	CRO5C	Ceftriaxone 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	CRO30C	Ceftriaxone 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	CT40C	Ceftolozone/Tazobactam 30-10	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	CXM5C	Cefuroxime 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	CXM30C	Cefuroxime 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CFX30C	Cephalexin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	CRD30C	Cephadrine 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	KF30C	Cephalothin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Certificate No: 932114



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
43	CZ30C	Cephazolin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
44	C10C	Chloramphenicol 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	C30C	Chloramphenicol 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
46	CIP1C	Ciprofloxacin 1ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	CIP5C	Ciprofloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	CLA2C	Clarithromycin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	CLA5C	Clarithromycin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	CLA15C	Clarithromycin 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	CD2C	Clindamycin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	CTM10C	Clotrimazole 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	CO10C/NCE	Colistin Sulphate 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	CO25C/NCE	Colistin Sulphate 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	DLX5C	Delafloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
56	DOR10C	Doripenem 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
57	DXT30C	Doxycycline 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	ECN10C	Econazole 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
59	ENF5C	Enrofloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	ERV20C	Eravacycline 20ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	ETP10C	Ertapenem 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
62	E5C	Erythromycin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	E15C	Erythromycin 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
64	FFC30C	Florfenicol 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
65	FOT200C	Fosfomycin200ug/Glucose 6 Phosphate 50ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
66	FCN10C	Fluconazole 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges





Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
67	FCN25C	Fluconazole 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
68	FCN25	Fluconazole 25ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
69	FY1C	Flucytosine 1ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
70	FC10C	Fusidic Acid 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
71	GM10C	Gentamicin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
72	GM30C	Gentamicin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
73	GM120C	Gentamicin 120ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
74	GM200C	Gentamicin 200ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
75	IM110C	Imipenem 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
76	K30C	Kanamycin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
77	KCA10C	Ketoconazole 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
78	LEV1C	Levofloxacin 1ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
79	LEV5C	Levofloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
80	LZD10C	Linezolid 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
81	LZD30C	Linezolid 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
82	MEC10C	Mecillinam 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
83	MEM10C	Meropenem 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
84	MEM10	Meropenem 10ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
85	MEV30C	Meropenem/Vaborbactam 20-10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
86	MZ5C	Metronidazole 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
87	MZ5	Metronidazole 5ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
88	MCL10C	Miconazole 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
89	MN30C	Minocycline 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
90	MFX1C	Moxifloxacin 1ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Certificate No: 932114



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
91	MF5C	Moxifloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
92	MUP5C	Mupirocin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
93	MUP20C	Mupirocin 20ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
94	MUP200C	Mupirocin 200ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
95	NA30C	Nalidixic Acid 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
96	NA30	Nalidixic Acid 30ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
97	NE10C	Neomycin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
98	NE30C	Neomycin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
99	NET10C	Netilmicin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
100	NET30C	Netilmicin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
101	NI100C	Nitrofurantoin 100ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
102	NI200C	Nitrofurantoin 200ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
103	NI300C	Nitrofurantoin 300ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
104	NIB30C	Nitroxoline 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
105	NOR2C	Norfloxacin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
106	NOR10C	Norfloxacin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
107	NO5C	Novobiocin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
108	NO5	Novobiocin 5ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
109	NY100	Nystatin 100 units	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
110	OFX5C	Ofloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
111	OX1C	Oxacillin 1ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
112	OX1	Oxacillin 1ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
113	PEF5C	Pefloxacin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
114	PG1C	Penicillin G 1 unit	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Certificate No: 932114



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
115	PG1	Penicillin G 1 unit	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
116	PRL30C	Piperacillin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
117	PRL75C	Piperacillin 75ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
118	PRL100C	Piperacillin 100ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
119	PTZ36C	Piperacillin/Tazobactam 30-6	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
120	PTZ85C	Piperacillin/Tazobactam 75-10	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
121	PTZ110C	Piperacillin/Tazobactam 100-10	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
122	PB300C	Polymyxin B 300 units	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
123	SYN15C	Quinupristin/dalfopristin 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
124	RP2C	Rifampicin 2ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
125	RP5C	Rifampicin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
126	RP5	Rifampicin 5ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
127	SPC25C	Spectinomycin 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
128	S10C	Sureptomycin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
129	S300C	Streptomycin 300ug Discs	5 x 50 discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
130	TEC30C	Teicoplanin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
131	TEL15C	Telithromycin 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
132	TEM30C	Temocillin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
133	T10C	Tetracycline 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
134	T10	Tetracycline 10ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
135	T30C	Tetracycline 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
136	TC75C	Ticarcillin 75ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
137	TGC15C	Tigecycline 15ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
138	TIM85C	Timentin 85ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Certificate No. 932114



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
139	TN10C	Tobramycin 10ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
140	TM2.5C	Trimethoprim 2.5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
141	TM5C	Trimethoprim 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
142	TS25C	Cotrimoxazole 25ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
143	TS25	Cotrimoxazole 25ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
144	VA5C	Vancomycin 5ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
145	VA5	Vancomycin 5ug	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
146	VA30C	Vancomycin 30ug	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
147	BD0680W/C	Blank discs	5 x 50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
148	BD0680W	Blank discs	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials







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## EC DECLARATION OF CONFORMITY

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This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various (DM---)	<b>MAST® Dehydrated culture media</b> – Powdered product formulations for use in microbial culture media.	Self certification Annex III excluding section 6	1401010100, 1401010200, 1403010100 (Codes registered - 24/03/2003)  GMDN codes 30630, 30660
Various (IDM---)	<b>MAST® ID culture media</b> – Powdered culture media formulations for use in microbial identification.	Self certification Annex III excluding section 6	1401010100, 1401010200 1403010100 (Codes registered - 24/03/2003)  GMDN codes 30630, 30660

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by ..... Date: 12 June 2019

D N Hogben, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 31 December 2021



European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD

EC DECLARATION OF CONFORMITY- Self-Certification (Annex III excluding section 6) – General IVD

Product Names: Mast Dehydrated Culture Media

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
1	DM630E	Anaerobe Isolation Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
2	DM095D	Baird-Parker Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
3	DM100D	Blood Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
4	DM100D	Blood Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
5	DM101D	Blood Agar Base-Special	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
6	DM101E	Blood Agar Base-Special	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
7	DM104D	Brain Heart Infusion Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
8	DM104E	Brain Heart Infusion Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
9	DM106D	Brain Heart Infusion Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
10	DM106E	Brain Heart Infusion Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
11	DM105-2D	Brilliant Green Agar (Modified Formula)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
12	DM105-2E	Brilliant Green Agar (Modified Formula)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
13	DM259E	Brilliant Green Bile (2%) Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
14	DM107E	Brucella Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
15	DM494D	Buffered Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
16	DM494E	Buffered Peptone Water	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
17	DM269D	Buffered Rappaport Vassiliadis Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
18	DM269E	Buffered Rappaport Vassiliadis Broth	Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
19	DM253D	Burkholderia cepacia Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
20	DM253E	Burkholderia cepacia Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
21	DM470D	C.E.M.O. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
22	DM470E	C.E.M.O. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
23	DM110D	C.L.E.D. Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	DM110E	C.L.E.D. Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	DM111D	C.L.E.D. with Andrade's Indicator	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	DM111E	C.L.E.D. with Andrade's Indicator	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
27	DM254E	Clostridium difficile Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	DM109D	Charcoal Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	DM109E	Charcoal Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	DM115D	Columbia Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
31	DM115E	Columbia Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	DM119D	Cooked Meat Granules	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	DM119E	Cooked Meat Granules	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	DM120D	Cooked Meat Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	DM120E	Cooked Meat Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	DM130D	D.C.A. (Hynes)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
27	DM130E	D.C.A. (Hynes)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	DM131D	D.C.A. (Leifsons)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	DM131E	D.C.A. (Leifsons)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	DM129D	D.C.L.S. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
31	DM129E	D.C.L.S. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	DM215D	D.S.T. Agar (Sulphonamide Antagonist Free)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	DM215E	D.S.T. Agar (Sulphonamide Antagonist Free)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
34	DM132D	DNase Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
35	DM132E	DNase Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
36	DM135D	Endo Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
37	DM135E	Endo Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
38	DM133D	Eosin Methylene Blue Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
39	DM133E	Eosin Methylene Blue Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
40	DM136D	G.C. Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
41	DM136E	G.C. Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
42	DM134D	Hektoen Enteric Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
42	DM134E	Hektoen Enteric Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
43	DM255E	Islams Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media

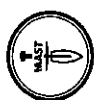


**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
44	DM137D	Kligler's Iron Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
45	DM137E	Kligler's Iron Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
46	DM258D	Legionella BCYE Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
47	DM258E	Legionella BCYE Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
48	DM256E	Listeria Selective Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
49	DM440D	M.S.R.V. (Salmonella) Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
50	DM440E	M.S.R.V. (Salmonella) Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
51	DM140D	MacConkey Agar (without salt)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
52	DM140E	MacConkey Agar (without salt)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
53	DM141D	MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
54	DM141E	MacConkey Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
55	DM142D	MacConkey Agar No.2	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
56	DM142E	MacConkey Agar No.2	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
57	DM143D	MacConkey Agar No.3	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
58	DM143E	MacConkey Agar No.3	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
59	DM150D	MacConkey Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
60	DM150E	MacConkey Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
61	DM160D	Mannitol Salt Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
62	DM160E	Mannitol Salt Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
63	DM170D	Mueller Hinton Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
64	DM170E	Mueller Hinton Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
65	DM171D	Mueller Hinton Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
66	DM171E	Mueller Hinton Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
67	DM179D	Nutrient Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
68	DM179E	Nutrient Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
69	DM180D	Nutrient Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
70	DM180E	Nutrient Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
71	DM184E	Peptone Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
72	DM185D	Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
73	DM185E	Peptone Water	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
74	DM195D	Plate Count Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
75	DM195E	Plate Count Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
76	DM251D	Preston Blood Free Campylobacter Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
77	DM251E	Preston Blood Free Campylobacter Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
78	DM205D	S.S. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
79	DM205E	S.S. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
80	DM200D	Sabouraud Dextrose Agar	500g	EDMS - 1401010100 GMDN - 30660	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
81	DM200E	Sabouraud Dextrose Agar	5Kg	EDMS - 1401010100 GMDN - 30660	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
82	DM211D	Simmons Citrate Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
83	DM211E	Simmons Citrate Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
84	DM491D	Sorbitol MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
85	DM491E	Sorbitol MacConkey Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media





Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
86	DM218D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
87	DM218E	T.C.B.S. Cholera Medium	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
88	DM219S	Tetrathionate Broth	460g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
89	DM221D	Thioglycollate Broth USP	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
90	DM221E	Thioglycollate Broth USP	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
91	DM224D	Triple Sugar Iron Agar (TSI)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
92	DM224E	Triple Sugar Iron Agar (TSI)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
93	DM225D	Tryptone Soy Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
94	DM225E	Tryptone Soy Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
95	DM226D	Tryptone Soy Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
96	DM226E	Tryptone Soy Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
97	DM228D	Urea Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
98	DM228E	Urea Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
99	DM228S	Urea Solution (40% v/v)	10 x10ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
100	DM493D	Violet Red Bile (Glucose) Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
101	DM493E	Violet Red Bile (Glucose) Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
102	DM480D	Violet Red Bile (Lactose) Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
103	DM480E	Violet Red Bile (Lactose) Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
104	DM235D	Wilkins Chalgren Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
104	DM235E	Wilkins Chalgren Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
105	DM230D	X.L.D. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
106	DM230E	X.L.D. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
107	DM496D	Yeast Extract Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
108	DM496E	Yeast Extract Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
109	DM702E	Yeast Glucose Chloramphenicol Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
110	DM252D	Yersinia Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
111	DM252E	Yersinia Agar Base	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**European In Vitro Diagnostic Medical Directive 98/79/EC,  
Annex III – General IVD**

**EC DECLARATION OF CONFORMITY - Self-Certification (Annex III excluding section 6) – General IVD  
Product Names: Mast Dehydrated Identification Media**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
1	IDM1/A	AMYGDALIN ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
2	IDM10/A	SUCROSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
3	IDM11/A	DULCITOL ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
4	IDM12/A	LACTOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
5	IDM13/A	XYLOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
6	IDM14/A	CARBOHYDRATE BASE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
7	IDM16/A	ADONITOL ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
8	IDM17/A	CELLOBIOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
9	IDM2/A	ARABINOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
10	IDM21/A	AESCULIN ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
11	IDM22/A	ADH ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
12	IDM23/A	CITRATE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
13	IDM24/A	GELATIN ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
14	IDM25/A	H2S ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
15	IDM26/A	LDC ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
16	IDM27/A	MALONATE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
17	IDM28/A	MOTILITY TEST AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
18	IDM29/A	ONPG ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
19	IDM3/A	GLUCOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
20	IDM30/A	ODC ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
21	IDM31/A	PHENYLALANINE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
22	IDM32/A	UREA ID AGAR BASE (MULTIPOINT)	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
23	IDM33/A	VP ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	IDM34/A	INDOLE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	IDM35/A	GLUCONATE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	IDM36/A	PSEUDOMONAS ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



**Mast  
Group**

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
27	IDM37/A	BETA GLUCURONIDASE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	IDM4/A	INOSITOL ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	• IDM40/L • IMM40D	CHROMagar CANDIDA	• 10x200ml sachets • 500g	EDMS - 1401010100 GMDN - 30660	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	IDM5/A	MALTOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
31	IDM6/A	MANNITOL ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	IDM7/A	MELIBIOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	IDM8/A	RHAMNOSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
35	IDM9/A	SUCROSE ID AGAR	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Holds Certificate Number:

FM 724380

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**Design, manufacture and supply of in-vitro diagnostic devices and associated services.**

For and on behalf of BSI:

\_\_\_\_\_  
Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31

Page: 1 of 2



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Certificate No: FM 724380

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices and associated services.
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacturing, QC and warehousing of IVD kits and reagents, bacteriological media and other kits and reagents for the life sciences industry.



Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Mast Group Ltd  
Mast House, Derby Road  
Bootle  
Liverpool  
L20 1EA  
United Kingdom

Holds Certificate Number:

**MD 724379**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media.

For and on behalf of BSI:

\_\_\_\_\_  
Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31



Page: 1 of 2

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Certificate No: **MD 724379**

Location	Registered Activities
Mast Group Ltd Mast House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media
Mast Group Ltd Atlantic House, Derby Road Bootle Liverpool L20 1EA United Kingdom	Manufacture of IVD kits and reagents for clinical microbiology and molecular biology, bacteriological media.



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

Page: 2 of 2

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## Mueller Hinton Agar

### DM170

#### Intended Use

A standardised medium for susceptibility testing.

#### Contents

See pack label.

#### Formulation\*

Material:	Concentration in medium:
Casein hydrolysate	17.5g/litre
Beef infusion from 300g	2.0g/litre
Starch	1.5g/litre
Agar	17.0g/litre
Final pH at 25°C: 7.3 ± 0.1	

#### Storage and shelf life

All dehydrated culture media containers should be kept tightly closed and stored in a dry place at 10 to 25°C until the expiry date shown on the pack label.

#### Precautions

For *in vitro* diagnostic use only. Observe approved hazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Refer to Product Safety Data sheet (available on request or via MAST® website).

#### Materials required but not provided

Standard microbiological supplies and equipment such as loops, MAST® selective supplements, swabs, applicator sticks, incinerators and incubators, etc., as well as serological and biochemical reagents and additives such as blood.

#### Procedure

1. Refer to pack label for quantities and volumes required. Prepare MAST® Mueller Hinton Agar (DM170D) by suspending the powder in distilled or deionised water. For sachet packs, dissolve the entire contents of the sachet in the volume shown on the label.
2. Autoclave at 121°C (15 p.s.i.) for 15 minutes.
3. If required cool to 50 to 55°C and hold at this temperature in a water bath. If required add 5 to 7% sterile defibrinated blood to enhance the growth of fastidious organisms or antibiotics (MAST® ADATAB) for dilution susceptibility test methods.
4. Alternative growth supplements can be used.
5. Pour culture plates (25ml per plate) and allow to set.
6. Prepared culture plates may be used immediately or stored in plastic bags at 2 to 8°C for up to one week before use.

7. Antimicrobial Susceptibility Testing should be performed in accordance with standards set down by regulatory bodies such as CLSI® (Clinical and Laboratory Standards Institute) and EUCAST (The European Committee on Antimicrobial Susceptibility Testing).

#### Interpretation of results

After incubation record diameter of zones of inhibition or Minimum Inhibitory Concentration (MIC). Interpret results as sensitive, intermediate or resistant according to the criteria laid down in the method of use.

#### Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate expected performance. Do not use the product if the result with the control organism is incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain.

Test Organisms	
<i>Enterococcus faecalis</i> ATCC® 29212	Growth and correct susceptibility pattern
<i>Escherichia coli</i> ATCC® 25922	Growth and correct susceptibility pattern
<i>Pseudomonas aeruginosa</i> ATCC® 27853	Growth and correct susceptibility pattern
<i>Staphylococcus aureus</i> ATCC® 25923	Growth and correct susceptibility pattern

#### References

Bibliography available on request.



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## MASTDISCS®

### Antimicrobial Susceptibility Test Discs

**MASTDISCS®.** An extensive range of individual antimicrobial susceptibility test discs in glass vials and plastic dispensing cartridges.

FOR IN VITRO DIAGNOSTIC USE ONLY

**Contents:** 100 discs in a vial or a pack of 5 cartridges each cartridge containing 50 discs.

#### Formulation\*

6mm diameter filter paper discs printed with an appropriate identification code of letters and/or numbers and impregnated with accurately assayed quantities of antimicrobial agent.

#### Storage and shelf life

Store at 2 to 8°C in the containers provided until the expiry date shown on the pack label. Allow to equilibrate to room temperature before opening. Return to the refrigerator promptly after use.

#### Precautions

For *in vitro* diagnostic use only. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Refer to Product Safety Data sheet.

#### Materials required but not provided

Standard microbiological supplies and equipment such as loops, MAST® culture media, swabs, applicator sticks, incinerators and incubators, etc., as well as serological and biochemical reagents and additives such as blood. Suitable interpretive criteria from standardised reference methods. MAST® DiscMaster Dispenser.

#### Procedure

**MASTDISCS®** should be used according to an appropriate standardised susceptibility test method. Various alternative methodologies are available and **MASTDISCS®** are compatible with these.

1. Remove the **MASTDISCS®** container from the refrigerator and allow to equilibrate to room temperature before opening.
2. Using a sterile needle or forceps, transfer each disc required onto the surface of a suitable plate of MAST® susceptibility test medium e.g. Mueller-Hinton Agar (DM170) dried and pre-inoculated with test organism according to the methodology followed.
3. If using **MASTDISCS®** in cartridges, load each cartridge required into a MAST® DiscMaster Dispenser.

4. Place the loaded DiscMaster Dispenser over the Petri Dish and dispense discs (see DiscMaster instructions for full details).
5. Incubate plates in air at 35 to 37°C for 18 to 24 hours (or alternative incubation conditions according to the methodology followed).
6. Measure (to the nearest whole mm) and record the diameter of any zones of inhibition that are observed around the antibiotic impregnated discs.

#### Interpretation of results

Interpret measured zones of inhibition by reference to published tables of critical zone diameter breakpoints provided by appropriate authorities and classify test isolate as Susceptible (S), Intermediate (I) or Resistant (R).

#### Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate a correct susceptibility pattern. Do not use the product if the reactions with the control organisms are incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain.

Test Organisms	
<i>Escherichia coli</i> ATCC® 25922	Correct susceptibility pattern*
<i>Pseudomonas aeruginosa</i> ATCC® 27853	Correct susceptibility pattern*
<i>Staphylococcus aureus</i> ATCC® 25923	Correct susceptibility pattern*

\*See appropriate quality control table

#### Limitations

Any deviation from the prescribed method may produce incorrect results.

**The latest published version of the method used should be consulted for complete details of test procedures and interpretive criteria.**

#### References

Bibliography available on request.