



Mast Group Ltd.
 Mast House
 Derby Road
 Bootle
 Merseyside L20 1EA
 United Kingdom
 Tel. +44 (0)151 933 7277
 Fax +44 (0)151 944 1332
 www.mastgrp.com

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 (DM---)	MAST® Dehydrated culture media – 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---)	MAST® ID culture media – 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

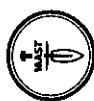


Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
13	DM259E	Brilliant Green Bile (2%) Broth	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture 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



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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



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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

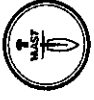


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Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
72	DM185D	Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - 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



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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**

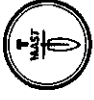
**EC DECLARATION OF CONFORMITY - Self-Certification (Annex III excluding section 6) – General IVD
Product Names: Mast Dehydrated Identification Media**

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
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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



Mast Group Ltd.
 Mast House
 Derby Road
 Bootle
 Merseyside L20 1EA
 United Kingdom
 Tel. +44 (0) 151 933 7277
 Fax +44 (0) 151 944 1332
 www.mastgrp.com


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', and are placed on the European market by Mast Group UK through our appointed EC Authorised Representative Mast Diagnostica GmbH, Feldstrasse 20, 23858 Reinfeld, Germany.

This declaration is valid for the IVD medical devices described below on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below which are manufactured by Mast 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
PACE-ID	MAST® CARBA PAcE – A screening test for the rapid detection of carbapenemase producing Enterobacterales, <i>Pseudomonas</i> , OXA 48 and 23-like enzyme production in <i>Acinetobacter</i> .	Self certification Annex III excluding section 6	1402029000 (code registered - 24/03/2003)

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: 31st December 2020

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

Document valid till: 26th May 2022

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



...making excellence a habit.™

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

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

...making excellence a habit.™

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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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.

MAST[®] CARBA PACe

Pseudomonas, *Acinetobacter*, Enterobacterales
Rapid carbapenemase detection



- Rapid results in less than 10 minutes
- Simple test process in 5 easy steps
- Cost effective screening solution
- High sensitivity and specificity

MAST[®] CARBA PAcE

An increase in antimicrobial resistance is one of the most urgent global challenges facing the field of healthcare. Healthcare associated infections (HAI) are one of the most common adverse effects in care delivery and the occurrences of epidemics of HAI are a major public health problem (WHO 2017).

Carbapenem resistant Gram negative bacteria, including Enterobacterales (CRE), *Pseudomonas aeruginosa* and *Acinetobacter baumannii* are an emerging cause of HAI and accordingly a global public healthcare concern due to high levels of antimicrobial resistance and ability for widespread transmission. It is important to recognise carriers quickly to prevent and control the spread in nosocomial and community settings and also to aid antibiotic stewardship.

MAST[®] CARBA PAcE

Mast Group Ltd. remains at the forefront of the fight against such threats and as such has developed a colorimetric test which rapidly detects carbapenemase producing *Pseudomonas* spp., *Acinetobacter* spp. and Enterobacterales using a novel chromogenic cephalosporin analogue for which there is a patent pending for its application.

The new **MAST[®] CARBA PAcE** is a simple cost effective screening solution providing fast results within 10 minutes, yet reliable in detecting carbapenemase production to support patient treatment. Additionally, no special equipment is required allowing it to be easily integrated into any laboratory workflows.

The basis of this colorimetric test is the hydrolysis of the chromogenic cephalosporin analogue, eliminating the effects of ESBL and AmpC enzymes using suitable inhibitor compounds, providing specific carbapenemase detection. Therefore only distinguishing epidemiologically significant carbapenem resistance, avoiding unnecessary patient isolation.

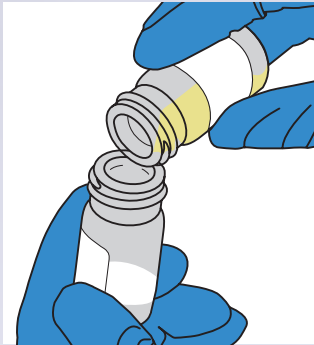
Benefits of MAST[®] CARBA PAcE

- | | |
|--|---|
| Rapid time to result | - Once the test organism is added to the test solution results are available within 10 minutes |
| Cost effective | - Conveniently contains 48 tests per kit, allowing quick identification of carbapenemase producers, assisting with prompt isolation of carriers to prevent cross transmission |
| Easily integrated into any laboratory | - Requiring only standard microbiological supplies making this adaptable to any laboratory workflows |
| Easy to Use | - Simple test procedure, with 5 simple steps (see figure 1), colour change from yellow to orange/red indicates carbapenemase activity |
| Quality | - Validated using a panel of organisms including VIM, IMP, NDM, OXA-48-like, OXA-23 and KPC high sensitivity and specificity of 96% and 91% respectively |
| Complementary molecular range | - Provides a quality first tier screen prior to molecular detection and characterisation using MAST ISOPLEX[®] CRE-ART . |

MAST[®] CARBA PACe

Simple test Process

Reconstitute



Reconstitute the pellet by tipping the entire contents of vial RB into vial PEL.



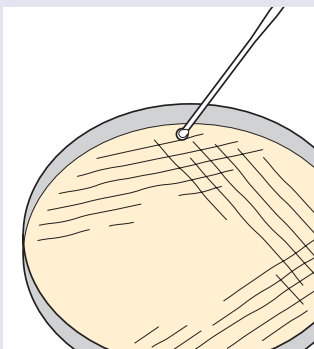
Allow the pellet to fully dissolve at room temperature for 1 minute and mix contents by gently vortexing for 10 seconds.

Dispense

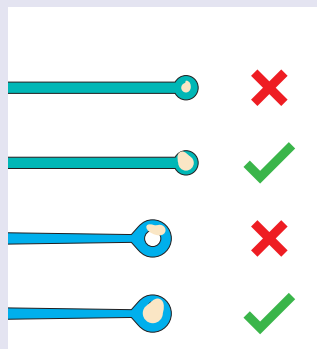


Dispense 250µl of reconstituted solution into the tubes provided. One tube per test.

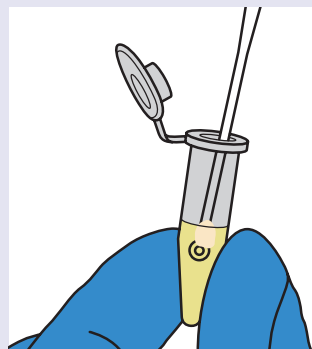
Inoculate



Use a pure, fresh culture of the test organism.



Take an approximate 1 - 5µl loopful of organism.

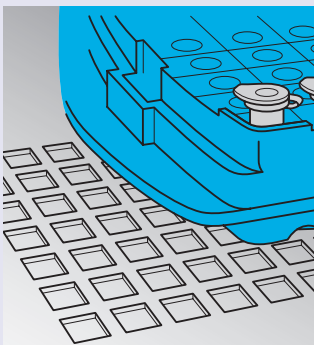


Add to the tube containing test solution.



Mix well by vortexing for 20 seconds.

Incubate



Incubate at 35±1°C for 10 minutes.

Read by eye



Record the colour of the test solution immediately or up to 20 minutes after incubation.

Ordering Information

Order Code	Product	Pack Size	No. Tests
PACE-ID	MAST [®] CARBA PAcE For the rapid detection of carbapenemase producing Enterobacterales, <i>Pseudomonas</i> spp. & <i>Acinetobacter</i> spp.	4 x 12 tests	48

Additional products from Masts AMR range

Order Code	Product	Pack Size	No. Tests
DNA/LYO5	MAST ISOPLEX [®] CRE-ART	10	10
D73C	MASTDISCS [®] Combi Carba plus	5 x 50 discs	50
D72C	MASTDISCS [®] Combi AmpC, ESBL & Carbapenemase Detection Set	6 x 50 discs	50
D74	MAST [®] ICT Indirect Carbapenemase Test	25	25
D71C	MASTDISCS [®] ID CAT-ID - Carbapenemase Activity Test	5 x 50 discs	250

References

Guidelines for the prevention and control of carbapenem-resistant Enterobacteriaceae, *Acinetobacter baumannii* and *Pseudomonas aeruginosa* in health care facilities. World Health Organisation 2017.

Acute trust toolkit for the early detection, management and control of carbapenemase-producing Enterobacteriaceae (Published: December 2013
PHE publications gateway number: 2013314)

Acknowledgement

HMRZ compound used in this product was developed by Dr. Hideaki Hanaki of Kitasato Institute, Japan.

ZT223 v3.0 CA 02/20

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

Tel: + 44 (0) 151 933 7277
Fax: + 44 (0) 151 944 1332
e-mail: sales@mast-group.com

Germany
Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld

Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
e-mail: mast@mast-diagnostica.de

France
Mast Diagnostic
12 Rue Jean-Jacques Mention
CS 91106
80011 Amiens CEDEX 1

Tél. + 33 (0) 322 80 80 67
Fax + 33 (0) 322 80 99 22
e-mail: info@mast-diagnostic.fr



Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
Fax: + 44 (0) 151 944 1332
email: sales@mast-group.com
Web: www.mast-group.com



Mast Diagnostica GmbH
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com



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.