



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
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

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by Christine Winstanley

Date: 26 May 2022

Christine Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 26th May 2025



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	DM095D	Baird-Parker Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
2	DM494D	Buffered Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
3	DM494E	Buffered Peptone Water	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
4	DM269D	Buffered Rappaport Vassiliadis Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
5	DM253D	Burkholderia cepacia Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
6	DM110A	C.L.E.D. Medium	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
7	DM110B	C.L.E.D. Medium	10x500ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
8	DM110D	C.L.E.D. Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
9	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
10	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
11	DM119E	Cooked Meat Granules	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	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
12	DM130D	D.C.A. (Hynes)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
13	DM215B	D.S.T. Agar (Sulphonamide Antagonist Free)	10x 500ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
14	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
15	DM132D	DNase Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
16	DM133D	Eosin Methylene Blue Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
17	DM136D	G.C. Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
18	DM134D	Hektoen Enteric Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
19	DM134E	Hektoen Enteric Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
20	DM146D	Kimmig Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
21	DM137D	Kligler's Iron Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
22	DM138-1D	Kohn's No 1 Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
23	DM258D	Legionella BCYE Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	DM440D	M.S.R.V. (Salmonella) Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	DM140D	MacConkey Agar (without salt)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	DM140E	MacConkey Agar (without salt)	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	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
27	DM141D	MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	DM141E	MacConkey Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	DM142D	MacConkey Agar No.2	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	DM143D	MacConkey Agar No.3	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
31	DM143E	MacConkey Agar No.3	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	DM150D	MacConkey Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	DM160D	Mannitol Salt Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
34	DM170B	Mueller Hinton Agar	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
35	DM170D	Mueller Hinton Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
36	DM170E	Mueller Hinton Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
37	DM171D	Mueller Hinton Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
38	DM171N	Mueller Hinton Broth	20Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
39	DM195D	Plate Count Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
40	DM251D	Preston Blood Free Campylobacter Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
41	DM205D	S.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	EMDS/GMDN Code	Brand Name	Intended purpose of the medical device type
42	DM205E	S.S. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
43	DM211D	Simmons Citrate Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
44	DM491D	Sorbitol MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
45	DM218D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
46	D401D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
47	DM219S	Tetrathionate Broth	460g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
48	DM221D	Thioglycollate Broth USP	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
49	DM224D	Triple Sugar Iron Agar (TSI)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
50	DM228D	Urea Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
51	DM228S	Urea Solution (40% v/v)	10 x10ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
52	DM480D	Violet Red Bile (Lactose) Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
53	DM235D	Wilkins Chalgren Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
54	DM230D	X.L.D. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
55	DM230E	X.L.D. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
56	DM496D	Yeast Extract Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media

IVD solutions through partnership



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Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN Code	Brand Name	Intended purpose of the medical device type
57	DM252D	Yersinia Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



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Product code	Product description	IVD Directive classification	EDMS code
Various	MAST DISCS® AST – paper antimicrobial susceptibility test (AST) disc products. Each disc contains an antimicrobial agent of stated content in conformance to recognised AST standards such as European Committee on Antimicrobial Susceptibility Testing - EUCAST or US Clinical and Laboratory Standards Institute - CLSI.	Self-certification Annex III excluding section 6	1402050200 (Code registered - 02/12/2002) GMDN code - 63834

Standards applied: EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 15223-2:2010.

Declaration made by 

Date: 18th May 2022

C Winstanley, Quality Assurance and Regulatory Affairs Manager – Mast Group Ltd.

Document valid till: 18th May 2025



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® Disc AST products

Annex – list of Mast® Disc AST products

Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
1	AK30C	Amikacin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
2	AP2C	Ampicillin 2ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
3	AP10C	Ampicillin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
4	SAM20C	Ampicillin 10ug/Sulbactam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
5	AUG3C	Amoxicillin/clavulanic acid 2-1	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
6	AUG30C	Amoxicillin/clavulanic acid 20-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
7	ATH15C	Azithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
8	ATM30C	Aztreonam 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
9	BA10C	Bacitracin 10 units	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
10	PY100C	Carbenicillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
11	CFC30C	Cefaclor 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
12	CFB30C	Ceftibuten 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
13	CMD30C	Cefamandole 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
14	CDX30C	Cefadroxil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
15	BPR5C	Ceftobiprole 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
16	CPM30C	Cefepime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
17	CFM5C	Cefixime 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
18	CPZ75C	Cefoperazone 75ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
19	CTX5C	Cefotaxime 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
20	CTX30C	Cefotaxime 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
22	CTF30C	Cefotiam 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	FOX30C	Cefoxitin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	CPD10C	Cefpodoxime 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CZL30	Cefprozil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CPT5C	Ceftaroline 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	CPT30C	Ceftaroline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	CZA14C	Ceftazidime/avibactam 10-4	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CZA50C	Ceftazidime/avibactam 30-20	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CAZ10C	Ceftazidime 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CAZ30C	Ceftazidime 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CRO5C	Ceftriaxone 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	CRO30C	Ceftriaxone 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	C/T40C	Ceftolozone/Tazobactam 30-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	CXM30C	Cefuroxime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	CFX30C	Cephalexin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	KF30C	Cephalothin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	CZ30C	Cephazolin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	C30C	Chloramphenicol 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	CIP5C	Ciprofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CLA15C	Clarithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	CD2C	Clindamycin 2ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	DLX5C	Delafloxacin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
43	DOR10C	Doripenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
44	DXT30C	Doxycycline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	ERV20C	Eravacycline 20ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
46	ETP10C	Ertapenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	E15C	Erythromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	FOT200C	Fosfomycin/Trometamol 200ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	FC10C	Fusidic Acid 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	FDC30C	Cefiderocol 30ug discs	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	GM10C	Gentamicin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	GM30C	Gentamicin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	GM120C	Gentamicin 120ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	IMI10C	Imipenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	IMR35C	Imipenem/relebactam 35µg discs	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
56	K30C	Kanamycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
57	LEV5C	Levofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	LZD10C	Linezolid 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
59	LZD30C	Linezolid 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	MEC10C	Mecillinam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	MEM10C	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
62	MEM10	Meropenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	MEV30C	Meropenem/Vaborbactam 20-10ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
64	MZ5C	Metronidazole 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
65	MZ5	Metronidazole 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
66	MN30C	Minocycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
67	MFX5C	Moxifloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



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Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
68	MUP200C	Mupirocin 200ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
69	NA30C	Nalidixic Acid 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
70	NA30	Nalidixic Acid 30ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
71	NE10C	Neomycin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
72	NET30C	Netilmicin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
73	NI100C	Nitrofurantoin 100ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
74	NI300C	Nitrofurantoin 300ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
75	NIB30C	Nitroxoline 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
76	NOR10C	Norfloxacin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
77	NO5C	Novobiocin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
78	OFX5C	Ofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
79	OX1C	Oxacillin 1ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
80	OX5C	Oxacillin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
81	OX1	Oxacillin 1ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
82	PEF5C	Pefloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
83	PG1C	Penicillin G 1 unit	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
84	PG1	Penicillin G 1 unit	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
85	PG10C	Penicillin G 10 unit	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
86	PG10	Penicillin G 10 unit	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
87	PRL30C	Piperacillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
88	PRL100C	Piperacillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
89	PTZ36C	Piperacillin/Tazobactam 30-6	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
90	PTZ110C	Piperacillin/Tazobactam 100-10	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
91	SYN15C	Quinupristin/dalfopristin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
92	RP5C	Rifampicin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
93	RP5	Rifampicin 5ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
94	SPC100C	Spectinomycin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
95	S10C	Streptomycin 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
96	S300C	Streptomycin 300ug Discs	EUCAST	5x50 discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
97	TEC30C	Teicoplanin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
98	TEL15C	Telithromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
99	TEM30C	Temocillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
100	T30C	Tetracycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
101	TC75C	Ticarcillin 75ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
102	TGC15C	Tigecycline 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
103	TIM85C	Timentin 85ug (Ticarcillin 75ug/Clavulanic acid 10ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
104	TN10C	Tobramycin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
105	TM5C	Trimethoprim 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
106	TS25C	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
107	TS25	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
108	VA5C	Vancomycin 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
109	VA5	Vancomycin 5ug	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
110	VA30C	Vancomycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges

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



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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

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

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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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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
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