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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	MAST DISCS [®] 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	IM10C	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

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	MAST® ID identification test paper products - discs, rings and strips. Products for presumptive identification of biochemical reactions or detection of a specific reaction profiles in microbes.	Self certification Annex III excluding section 6	1402020100, 1402020200, 1402020400, 1402020800, 1402029000. (codes 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



**Mast
Group**

**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**

Annex – list of MAST® ID identification test paper products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	D40C	Bacitracin Discs 0.04 units	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
2	D40	Bacitracin Discs 0.04 units	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
3	D41C	Bacitracin Discs 0.1 Unit	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
4	D41	Bacitracin Discs 0.1 Unit	100 Discs	MASTDISCS® ID	For presumptive Identification of Group A streptococci.
5	D42C	Optochin Discs 5ug	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
6	D42	Optochin Discs 5ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Strep. pneumoniae.
7	D43C	X Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
8	D43	X Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
9	D44C	V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
10	D44	V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
11	D45C	X+V Factor Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
12	D45	X+V Factor Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
13	D46C	Metronidazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
14	D46	Metronidazole Discs 50ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
15	D47C	Sulphathiazole Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
16	D47	Sulphathiazole Discs 1ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Gardnerella vaginalis.
17	D48	Lysostaphin Discs 20ug	50 Discs	MASTDISCS® ID	For presumptive Identification of Staphylococci/micrococci.
18	D49	ALA Discs 75ug	100 Discs	MASTDISCS® ID	For presumptive Identification of Haemophilus spp.
19	D51C	Nitrate Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in anaerobes.
20	D52C	Extended Spectrum β Lactamase Set	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
21	D55C	SPS Identification Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in P. anaerobius.
22	D55	SPS Discs 1000ug	100 Discs	MASTDISCS® ID	For presumptive Identification of P. anaerobius
23	D57C	Oxidase Discs	5 x 50 Discs	MASTDISCS® ID	For presumptive Identification of Nitrate Reductase in Pseudomonas spp.
24	D57	Oxidase Discs	100 Discs	MASTDISCS® ID	For presumptive Identification of Pseudomonas spp.
25	D59	Nitrocefin Discs (B)	50 Discs	MASTDISCS® ID	For presumptive Identification of Beta lactamase activity.
26	D62C	Cefotaxime 30 & Cefotaxime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.



Serial No.	Device ID	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
27	D63C	Cefepime 30 & Cefepime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
28	D64C	Ceftazidime 30 & Ceftazidime 30/Clavulanic Acid 10	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
29	D66C	Cefpodoxime 10 & Cefpodoxime 10/Clavulanic Acid 1	6 x 50 Discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
30	D67C	Extended Spectrum β Lactamase Set (CPD10)	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
31	D68C	AmpC & ESBL Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
32	D69C	AmpC Detection Set	3 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
33	D70C	Carbapenemase Detection Set	4 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
34	D71C	CAT ID - Carbapenemase Activity Test (CAT) discs	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
35	D72C	MastDiscs® Combi AmpC, ES β L and Carbapenemase Detection Disc Set	6 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
36	D73C	Carba Plus. For the detection of carbapenemase and OXA-48 enzyme production in Enterobacteriaceae.	5 X 50 discs	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
37	D74	MastDiscs® ID Indirect Carbapenemase Test (ICT)	25 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
38	D76C	MastDiscs® Combi ESBL Detection Set	50 Tests	MASTDISCS® Combi	Combination disc sets for the detection of antibiotic resistance.
39	STOX	Oxacillin Strips	50 Strips	MAST® ID	Oxacillin Strips for the detection of MRSA-Antibiotic Susceptibility Testing.
40	ETO/1	MAST® ID Intralactam Strips	25 strips	MAST® ID	A strip test for the rapid detection of β -lactamase.
41	ETO2	MAST® ID Intralactam Circles	10 circles	MAST® ID	A test for the detection of β -lactamase production. For use on multipoint inoculated plates.
42	ETO4	MAST® ID Oxidase Strips - for the performance of the oxidase reaction	25 strips	MAST® ID	A strip test for the rapid detection of cytochrome oxidase enzyme (Oxidase) in bacteria.



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
43	ETO7	MAST® ID PYR Strips - for the detection of pyrrolidonyl amino peptidase activity	25 strips	MAST-ID	A rapid strip test for the detection of pyrrolidonyl amino peptidase activity in streptococci and enterococci.
44	MIID/XV	MAST® ID XV Mirror ring. MASTRING™ containing X+V factor tips	50 rings	ID-MASTRING	For the identification of haemophilus spp.
45	MID8	MASTRING containing Erythromycin (60ug), Rifampicin (15ug), Colistin Sulphate (10ug), Penicillin G 2 units, Kanamycin (1000ug), Vancomycin (5ug)	50 rings	ID-MASTRING	For the presumptive identification of Gram negative non-sporing anaerobes.
46	MID/STAPH	MASTRING containing Desferrioxamine (1000ug), Novobiocin (5ug), para-Nitro Phenol Phosphate.	50 rings	ID-MASTRING	For the presumptive identification of coagulase negative staphylococci.
47	TEM30C	Temocillin Discs 30ug	5 x 50 Discs	MASTDISCS® ID	To aid presumptive Identification of OXA-48.
48	K1000C	Kanamycin 1000ug	5 x 50 Discs	MASTDISCS®	To aid the differentiation of anaerobic bacteria.



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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', 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	MAST DISCS® AST – paper antimicrobial susceptibility test (AST) disc products. Each disc contains an antimicrobial agent of stated content in conformance to a recognised AST standard 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 - 17005

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: 03rd March 2021

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

Document valid till: 26th May 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	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	AMB20C	Amphotericin B 20ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
3	AP2C	Ampicillin 2ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
4	AP10C	Ampicillin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
5	SAM20C	Ampicillin10ug/Sulbactam10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
6	AUG3C	Amoxicillin/clavulanic acid 2-1	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
7	AUG30C	Amoxicillin/clavulanic acid 20-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
8	ATH15C	Azithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
9	ATM30C	Aztreonam 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
10	BA8	Bacitracin 10 units	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
11	BA10C	Bacitracin 10 units	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
12	PY100C	Carbenicillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
13	CFC30C	Cefaclor 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
14	CFB30C	Ceftibuten 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
15	CMD30C	Cefamandole 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
16	CDX30C	Cefadroxil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
17	CPM30C	Cefepime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
18	CFM5C	Cefixime 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
19	CPZ75C	Cefoperazone 75ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
20	CTX5C	Cefotaxime 5ug	EUCAST	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
21	CTX30C	Cefotaxime 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
22	CTF30C	Cefotiam 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
23	FOX30C	Cefoxitin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
24	CPD10C	Cefpodoxime 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
25	CZL30	Cefprozil 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
26	CPT5C	Ceftaroline 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
27	CPT30C	Ceftaroline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
28	CZA14C	Ceftazidime/avibactam 10-4	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
29	CZA50C	Ceftazidime/avibactam 30-20	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
30	CAZ10C	Ceftazidime 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
31	CAZ30C	Ceftazidime 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
32	CRO5C	Ceftriaxone 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
33	CRO30C	Ceftriaxone 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
34	C/T40C	Ceftolozone/Tazobactam 30-10	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
35	CXM30C	Cefuroxime 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
36	CFX30C	Cephalexin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
37	KF30C	Cephalothin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
38	CZ30C	Cephazolin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
39	C30C	Chloramphenicol 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
40	CIP5C	Ciprofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
41	CLA15C	Clarithromycin 15ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
42	CD2C	Clindamycin 2ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
43	CTM10C	Clotrimazole 10ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
44	CO10C/NCE	Colistin Sulphate 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
45	DLX5C	Delafloxacin 5ug	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
46	DOR10C	Doripenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
47	DXT30C	Doxycycline 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
48	ECN10C	Econazole 10ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
49	ERV20C	Eravacycline 20ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
50	ETP10C	Ertapenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
51	E15C	Erythromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
52	FOT200C	Fosfomycin200ug/Glucose 6 Phosphate 50ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
53	FCN10C	Fluconazole 10ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
54	FCN25C	Fluconazole 25ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
55	FCN25	Fluconazole 25ug	Antifungal	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
56	FY1C	Flucytosine 1ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
57	FC10C	Fusidic Acid 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
58	FDC30C	Cefiderocol 30ug discs	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
59	GM10C	Gentamicin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
60	GM30C	Gentamicin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
61	GM120C	Gentamicin 120ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
62	IM110C	Imipenem 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
63	IMR35C	Imipenem/relebactam 35ug discs	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
64	K30C	Kanamycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
65	KCA10C	Ketoconazole 10ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
66	LEV5C	Levofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
67	LZD10C	Linezolid 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
68	LZD30C	Linezolid 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
69	MEC10C	Mecillinam 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
70	MEM10C	Meropenem 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
71	MEM10	Meropenem 10ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
72	MEV30C	Meropenem/Vaborbactam 20-10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
73	MZ5C	Metronidazole 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
74	MZ5	Metronidazole 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
75	MCL10C	Miconazole 10ug	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
76	MN30C	Minocycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
77	MF5C	Moxifloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
78	MUP200C	Mupirocin 200ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
79	NA30C	Nalidixic Acid 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
80	NA30	Nalidixic Acid 30ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
81	NE10C	Neomycin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
82	NET10C	Netilmicin 10ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
83	NET30C	Netilmicin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
84	NI100C	Nitrofurantoin 100ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
85	NI300C	Nitrofurantoin 300ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
86	NIB30C	Nitroxoline 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
87	NOR10C	Norfloxacin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
88	NO5C	Novobiocin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
89	NO5	Novobiocin 5ug	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
90	NY100C	Nystatin 100 units	Antifungal	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
91	NY100	Nystatin 100 units	Antifungal	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
92	OFX5C	Ofloxacin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
93	OX1C	Oxacillin 1ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
94	OX5C	Oxacillin 5ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
95	OX1	Oxacillin 1ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials



Serial No.	Device ID Number	Product Description	Method of use	Pack Size	Brand Name	Intended purpose of the medical device type
96	PG1	Penicillin G 1 unit	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
97	PG10C	Penicillin G 10 unit	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
98	PG10	Penicillin G 10 unit	CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
99	PRL30C	Piperacillin 30ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
100	PRL100C	Piperacillin 100ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
101	PTZ36C	Piperacillin/Tazobactam 30-6	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
102	PTZ110C	Piperacillin/Tazobactam 100-10	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
103	SYN15C	Quinupristin/dalfopristin15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
104	RP5C	Rifampicin 5ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
105	RP5	Rifampicin 5ug	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
106	RAX40C	Rifaximin 40ug	MAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
107	SPC100C	Spectinomycin 100ug	CLSI Vet	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
108	S10C	Streptomycin 10ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
109	S300C	Streptomycin 300ug Discs	EUCAST	5x50 discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
110	TEC30C	Teicoplanin 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
111	TEL15C	Telithromycin 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
112	TEM30C	Temocillin 30ug	MAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
113	T30C	Tetracycline 30ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
114	TC75C	Ticarcillin 75ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
115	TGC15C	Tigecycline 15ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
116	TIM85C	Timentin 85ug (Ticarcillin 75ug/Clavulanic acid 10ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
117	TN10C	Tobramycin 10ug	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
118	TM5C	Trimethoprim 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
119	TS25C	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
120	TS25	Cotrimoxazole 25ug (Trimethoprim 1.25ug/Sulphamethosazole 23.75ug)	EUCAST/CLSI	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
121	VA5C	Vancomycin 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
122	VA5	Vancomycin 5ug	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
123	VA30C	Vancomycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
124	BD0680W/C	Blank discs	N/A	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
125	BD0680W	Blank discs	N/A	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**Mast Group Limited
Mast House, Derby Road,
Bootle, Merseyside
United Kingdom**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0932114/C

Original Approval: 25 May 2004

Current Certificate: 1 June 2018

Certificate Expiry: 31 May 2021

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 0932114/C SCHEDULE

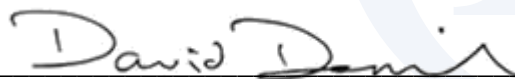
has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

**Mast Group Limited
Mast House, Derby Road,
Bootle, Merseyside
United Kingdom**

Annex II List B Products

Mastazyme CMV Kit, EIA 802

Schedule Issue: 01
Date of Schedule Issue: 1 June 2018
LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited

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

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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.
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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

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