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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	Ampicillin 10ug/Sulbactam 10ug	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





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



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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	Flufenical 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



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



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Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
91	MFX5C	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



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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	Siveptomycin 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	Ticarillin 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





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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