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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	<b>MAST DISCS®</b> 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 *Q Winstanley* Date: 18<sup>th</sup> May 2022

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

Document valid till: 18<sup>th</sup> 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	Ampicillin10ug/Sulbactam10ug	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





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 Cartridges
108	VA5C	Vancomycin 5ug	EUCAST	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Vials
109	VA5	Vancomycin 5ug	EUCAST	100 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges
110	VA30C	Vancomycin 30ug	CLSI	5x50 Discs	MASTDISCS	Antibiotic Susceptibility Testing Discs in Cartridges





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Product code	Product description	IVD Directive classification	EDMS code
Various (M-----)	<b>MAST® ASSURE Haemophilus influenzae Antisera</b> – for serological identification and epidemiological typing of <i>Haemophilus influenzae</i> .	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003)  GMDN code 43353

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 C Winstanley Date: 26<sup>th</sup> May 2022

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

Document valid till: 26<sup>th</sup> 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: MAST® ASSURE Haemophilus influenzae Antisera

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M11302	2ml	MAST® ASSURE Haemophilus influenzae Type a	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.
2	M11303	2ml	MAST® ASSURE Haemophilus influenzae Type b	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.
3	M11304	2ml	MAST® ASSURE Haemophilus influenzae Type c	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.
4	M11305	2ml	MAST® ASSURE Haemophilus influenzae Type d	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.
5	M11306	2ml	MAST® ASSURE Haemophilus influenzae Type e	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.
6	M11307	2ml	MAST® ASSURE Haemophilus influenzae Type f	Liquid stable antiserum for the determination of capsular-type specific antigens of Haemophilus influenzae by slide agglutination.





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Product code	Product description	IVD Directive classification	EDMS code/ GMDN code
Various (M-----)	<b>MAST® ASSURE Salmonella Antisera</b> – for serological identification and epidemiological typing of Salmonella bacteria.	Self certification Annex III excluding section 6	EDMS code - 1501000000 (code registered - 24/03/2003)  GMDN code - 39521

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 Cristianley Date: 26<sup>th</sup> May 2022

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

Document valid till: 26<sup>th</sup> 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® ASSURE Salmonella Antisera**

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M10308	2ml	MAST® ASSURE Salmonella O - POLY O Factor O2, O4, O7, O8, O9, O9, 46, O3, 10, O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
2	M10309	2ml	MAST® ASSURE Salmonella O - POLY O1 Factor O11, O13, O6, 14, O16, O18, O21, O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
3	M14294	2ml	MAST® ASSURE Salmonella O - POLY O A-G	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
4	M14300	2ml	MAST® ASSURE Salmonella O - POLY O A-S	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
5	M92537	2ml	MAST® ASSURE Salmonella O - Omnivalent (Kauffmann-White group A-067)	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
6	M14317	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 1&2 (a-z29)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
7	M10339	2ml	MAST® ASSURE Salmonella H - POLYVALENT PHASE 2 (H-1)	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
8	M14324	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 1 Factors b, d, E, r	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
9	M14331	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 2 Factors b, E, k, l	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.
10	M14348	2ml	MAST® ASSURE Salmonella H - RAPID DIAGNOSTIC 3 Factors d, E, G, k	Liquid stable polyvalent antiserum for the determination of H antigens for the serological identification of salmonellae by slide agglutination.





Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
11	M10310	2ml	MAST® ASSURE Salmonella O - Mono Factor O2	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
12	M10311	2ml	MAST® ASSURE Salmonella O - Mono Factor O4	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
13	M10312	2ml	MAST® ASSURE Salmonella O - Mono Factor O7	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
14	M10313	2ml	MAST® ASSURE Salmonella O - Mono Factor O8	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
15	M10314	2ml	MAST® ASSURE Salmonella O - Mono Factor O9	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
16	M10315	2ml	MAST® ASSURE Salmonella O - Mono Factor O9,46	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
17	M10316	2ml	MAST® ASSURE Salmonella O - Mono Factor O3,10	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
18	M10318	2ml	MAST® ASSURE Salmonella O - Mono Factor O1,3,19	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
19	M10319	2ml	MAST® ASSURE Salmonella O - Mono Factor O11	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
20	M10320	2ml	MAST® ASSURE Salmonella O - Mono Factor O13	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
21	M10321	2ml	MAST® ASSURE Salmonella O - Mono Factor O6,14	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
22	M10322	2ml	MAST® ASSURE Salmonella O - Mono Factor O16	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
23	M10323	2ml	MAST® ASSURE Salmonella O - Mono Factor O18	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
24	M10324	2ml	MAST® ASSURE Salmonella O - Mono Factor O21	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
25	M10325	2ml	MAST® ASSURE Salmonella O - Mono Factor O35	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
26	M10326	2ml	MAST® ASSURE Salmonella O - Mono Factor Vi	Liquid stable antiserum for the determination of Vi antigens for the serological identification of salmonellae by slide agglutination.





Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
27	M10327	2ml	MAST® ASSURE Salmonella H - Mono Factor a	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
28	M10328	2ml	MAST® ASSURE Salmonella H - Mono Factor b	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
29	M10329	2ml	MAST® ASSURE Salmonella H - Mono Factor c	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
30	M10330	2ml	MAST® ASSURE Salmonella H - Mono Factor d	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
31	M10331	2ml	MAST® ASSURE Salmonella H - Mono Factor e, h	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
32	M14335	2ml	MAST® ASSURE Salmonella H - Mono Factor E	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
33	M10332	2ml	MAST® ASSURE Salmonella H - Mono Factor G	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
34	M10333	2ml	MAST® ASSURE Salmonella H - Mono Factor i	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
35	M10334	2ml	MAST® ASSURE Salmonella H - Mono Factor k	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
36	M10336	2ml	MAST® ASSURE Salmonella H - Mono Factor r	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
37	M10344	2ml	MAST® ASSURE Salmonella H - Mono Factor 2	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
38	M10345	2ml	MAST® ASSURE Salmonella H - Mono Factor 5	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
39	M10346	2ml	MAST® ASSURE Salmonella H - Mono Factor 6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
40	M10364	2ml	MAST® ASSURE Salmonella H - Mono Factor f	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
41	M10365	2ml	MAST® ASSURE Salmonella H - Mono Factor m	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
42	M10366	2ml	MAST® ASSURE Salmonella H - Mono Factor p	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.





Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
43	M10367	2ml	MAST® ASSURE Salmonella H - Mono Factor q	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
44	M10368	2ml	MAST® ASSURE Salmonella H - Mono Factor s	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
45	M10369	2ml	MAST® ASSURE Salmonella H - Mono Factor t	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
46	M10376	2ml	MAST® ASSURE Salmonella H - Mono Factor x	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
47	M10335	2ml	MAST® ASSURE Salmonella H - Mono Factor L	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
48	M10337	2ml	MAST® ASSURE Salmonella H - Mono Factor y	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
49	M10338	2ml	MAST® ASSURE Salmonella H - Mono Factor e,n	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
50	M10340	2ml	MAST® ASSURE Salmonella H - Mono Factor v	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
51	M10341	2ml	MAST® ASSURE Salmonella H - Mono Factor w	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
52	M10342	2ml	MAST® ASSURE Salmonella H - Mono Factor z13	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
53	M10343	2ml	MAST® ASSURE Salmonella H - Mono Factor z28	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
54	M10347	2ml	MAST® ASSURE Salmonella H - Mono Factor 7	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
55	M10348	2ml	MAST® ASSURE Salmonella H - Mono Factor z6	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
56	M10370	2ml	MAST® ASSURE Salmonella H - Mono Factor u	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
57	M10372	2ml	MAST® ASSURE Salmonella H - Mono Factor z23	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
58	M10373	2ml	MAST® ASSURE Salmonella H - Mono Factor z24	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
59	M10377	2ml	MAST® ASSURE Salmonella H - Mono Factor z15	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
60	M10374	2ml	MAST® ASSURE Salmonella H - Mono Factor z32	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
61	M10378	2ml	MAST® ASSURE Salmonella H - Mono Factor z	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
62	M10379	2ml	MAST® ASSURE Salmonella H - Mono Factor z4	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
63	M10380	2ml	MAST® ASSURE Salmonella H - Mono Factor z10	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
64	M10381	2ml	MAST® ASSURE Salmonella H - Mono Factor z29	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.





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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 (M-----)	<b>MAST® ASSURE Shigella Antisera</b> – for serological identification and epidemiological typing and grouping of Shigella species.	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003)  GMDN code - 39452

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 C Winstanley Date: 26<sup>th</sup> May 2022

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

Document valid till: 26<sup>th</sup> 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® ASSURE Shigella Antiserum

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M10109	2ml	MAST® ASSURE Shigella dysenteriae POLY A Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
2	M10110	2ml	MAST® ASSURE Shigella dysenteriae POLY A1 Types 8, 9, 10, 11, 12	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
3	M10111	2ml	MAST® ASSURE Shigella flexneri POLY B Types I, II, III, IV, V, VI, (Groups(3)4,6&7(8)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
4	M10112	2ml	MAST® ASSURE Shigella boydii POLY C Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
5	M10113	2ml	MAST® ASSURE Shigella boydii POLY C1 Types 8, 9, 10, 11	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
6	M10114	2ml	MAST® ASSURE Shigella boydii POLY C2 Types 12, 13, 14, 15	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
7	M10154	2ml	MAST® ASSURE Shigella boydii POLY C3 Types 16, 17, 18	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
8	M10115	2ml	MAST® ASSURE Shigella sonnei POLY D Phase I & II	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella sonnei by slide agglutination.





Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
9	M10116	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 1	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
10	M10117	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 2	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
11	M10118	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
12	M10119	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
13	M10120	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
14	M10121	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
15	M10122	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
16	M10123	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
17	M10124	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
18	M10125	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
19	M10152	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
20	M10153	2ml	MAST® ASSURE Shigella dysenteriae - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
21	M10126	2ml	MAST® ASSURE Shigella flexneri - Mono Type I	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
22	M10127	2ml	MAST® ASSURE Shigella flexneri - Mono Type II	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
23	M10128	2ml	MAST® ASSURE Shigella flexneri - Mono Type III	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
24	M10129	2ml	MAST® ASSURE Shigella flexneri - Mono Type IV	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
25	M10130	2ml	MAST® ASSURE Shigella flexneri - Mono Type V	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
26	M10131	2ml	MAST® ASSURE Shigella flexneri - Mono Type VI	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
27	M10132	2ml	MAST® ASSURE Shigella flexneri - Mono Group (3)4	Liquid stable antisera for the determination of O antigen group for the serological identification of Shigella.
28	M10133	2ml	MAST® ASSURE Shigella flexneri - Mono Group 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
29	M10134	2ml	MAST® ASSURE Shigella flexneri - Mono Group 7 (8)	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.





Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
30	M10135	2ml	MAST® ASSURE Shigella boydii - Mono Type 1	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
31	M10136	2ml	MAST® ASSURE Shigella Boydii - Mono Type 2	Liquid stable antiserum for the determination of O antigen types for the serological identification of Shigella.
32	M10137	2ml	MAST® ASSURE Shigella boydii - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
33	M10138	2ml	MAST® ASSURE Shigella boydii - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
34	M10139	2ml	MAST® ASSURE Shigella boydii - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
35	M10140	2ml	MAST® ASSURE Shigella boydii - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
36	M10141	2ml	MAST® ASSURE Shigella boydii - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
37	M10142	2ml	MAST® ASSURE Shigella boydii - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
38	M10143	2ml	MAST® ASSURE Shigella boydii - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
39	M10144	2ml	MAST® ASSURE Shigella boydii - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
40	M10145	2ml	MAST® ASSURE Shigella boydii - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
41	M10146	2ml	MAST® ASSURE Shigella boydii - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
42	M10147	2ml	MAST® ASSURE Shigella boydii - Mono Type 13	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
43	M10148	2ml	MAST® ASSURE Shigella boydii - Mono Type 14	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
44	M10149	2ml	MAST® ASSURE Shigella boydii - Mono Type 15	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
45	M10155	2ml	MAST® ASSURE Shigella boydii - Mono Type 16	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.



Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
46	M10156	2ml	MAST® ASSURE Shigella boydii - Mono Type 17	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
47	M10157	2ml	MAST® ASSURE Shigella boydii - Mono Type 18	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.

Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
48	M10150	2ml	MAST® ASSURE Shigella sonnei - Mono Phase I	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.
49	M10151	2ml	MAST® ASSURE Shigella sonnei - Mono Phase II	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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

Holds Certificate Number:

FM 724380

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

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

For and on behalf of BSI:

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

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 724380

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



Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31

Page: 2 of 2

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An electronic certificate can be authenticated [online](#).  
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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.  
A Member of the BSI Group of Companies.



# Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

**MD 724379**

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

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

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31



Page: 1 of 2

...making excellence a habit.™

Certificate No: **MD 724379**

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



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

Page: 2 of 2

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E. coli  
Salmonella  
Haemophilus

# **mast**assure™

**Bacterial Agglutinating Antisera  
and Febrile Antigens**

Shigella  
Vibrio  
Campylobacter  
**Bordetella**  
Clostridium  
Legionella  
Pseudomonas  
Staphylococcus  
Listeria  
Streptococcus  
Yersinia  
**Proteus**  
Brucella



- High quality performance
- Reliable identification
- Easy to read
- Extensive range available

Order No	Product	Packsize
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**MAST ASSURE™ ANTISERA - STOCK LIST**

All stock antisera are CE marked for IVD use

**E.COLI O ANTISERA - MONOVALENT**

M12014	<i>Escherichia coli</i> Factor	O26	2ml
M12016	<i>Escherichia coli</i> Factor	O111	2ml
M12017	<i>Escherichia coli</i> Factor	O119	2ml
M12018	<i>Escherichia coli</i> Factor	O127a	2ml
M12030	<i>Escherichia coli</i> Factor	O157	2ml

**E.COLI O ANTISERA - POLYVALENT**

M14263	<i>E.coli</i> POLY 2 Factors O26, O55, O111, O119, O126		2ml
M14270	<i>E.coli</i> POLY 3 Factors O86, O114, O125, O127, O128		2ml
M14287	<i>E.coli</i> POLY 4 Factors O44, O112, O124, O142		2ml

**HAEMOPHILUS INFLUENZAE ANTISERA**

M11303	<i>H.influenzae</i> Type b		2ml
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**SALMONELLA O ANTISERA - MONOVALENT**

M10310	Salmonella O Factor	O2	2ml
M10311	Salmonella O Factor	O4	2ml
M10312	Salmonella O Factor	O7	2ml
M10313	Salmonella O Factor	O8	2ml
M10314	Salmonella O Factor	O9	2ml
M10316	Salmonella O Factor	O3,10	2ml
M10320	Salmonella O Factor	O13	2ml
M10321	Salmonella O Factor	O6,14	2ml
M10326	Salmonella O Factor	Vi	2ml

**SALMONELLA H ANTISERA - MONOVALENT**

M10327	Salmonella H Factor	a	2ml
M10328	Salmonella H Factor	b	2ml
M10329	Salmonella H Factor	c	2ml
M10330	Salmonella H Factor	d	2ml
M10331	Salmonella H Factor	e, h	2ml
M14335	Salmonella H Factor	E	2ml
M10332	Salmonella H Factor	G	2ml
M10333	Salmonella H Factor	i	2ml
M10334	Salmonella H Factor	k	2ml
M10336	Salmonella H Factor	r	2ml
M10344	Salmonella H Factor	2	2ml
M10345	Salmonella H Factor	5	2ml
M10346	Salmonella H Factor	6	2ml
M10364	Salmonella H Factor	f	2ml
M10365	Salmonella H Factor	m	2ml
M10366	Salmonella H Factor	p	2ml
M10367	Salmonella H Factor	q	2ml
M10368	Salmonella H Factor	s	2ml
M10369	Salmonella H Factor	t	2ml





**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**BORDETELLA ANTISERA**

M11501/NCE	This antiserum agglutinates Phase I <i>B.pertussis</i> but does not agglutinate Phase III <i>B.pertussis</i> , <i>B.parapertussis</i> , nor <i>B.bronchiseptica</i> .	No CE Mark	2ml
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**CAMPYLOBACTER ANTISERA**

M13001	<b>Campylobacter Antisera Set</b> Reagents for the serotyping of Campylobacter by a passive haemagglutination (PHA) method. This set consists of: 2ml each of antisera (groups A, B, C, D, E, F, G, I, J, K, L, N, O, P, R, S, U, V, Y, Z, Z2, Z4, Z5, Z6 and Z7) 2ml x 1 vial of reference antiserum for red blood cells.		26 x 2ml
M13002	Campylobacter group A antiserum		2ml
M13003	Campylobacter group B antiserum		2ml
M13004	Campylobacter group C antiserum		2ml
M13005	Campylobacter group D antiserum		2ml
M13006	Campylobacter group E antiserum		2ml
M13007	Campylobacter group F antiserum		2ml
M13008	Campylobacter group G antiserum		2ml
M13009	Campylobacter group I antiserum		2ml
M13010	Campylobacter group J antiserum		2ml
M13011	Campylobacter group K antiserum		2ml
M13012	Campylobacter group L antiserum		2ml
M13013	Campylobacter group N antiserum		2ml
M13014	Campylobacter group O antiserum		2ml
M13015	Campylobacter group P antiserum		2ml
M13016	Campylobacter group R antiserum		2ml
M13017	Campylobacter group S antiserum		2ml
M13018	Campylobacter group U antiserum		2ml
M13019	Campylobacter group V antiserum		2ml
M13020	Campylobacter group Y antiserum		2ml
M13021	Campylobacter group Z antiserum		2ml
M13022	Campylobacter group Z2 antiserum		2ml
M13023	Campylobacter group Z4 antiserum		2ml
M13024	Campylobacter group Z5 antiserum		2ml
M13025	Campylobacter group Z6 antiserum		2ml
M13026	Campylobacter group Z7 antiserum		2ml
M13027	Reference antiserum		2ml
M42201	<b>Reagent for preparing Sensitized Blood Cells</b> Fixed Chick RBCs Extraction Reagent-1 Extraction Reagent-2 Extraction Reagent-3 Buffer solution		50 tests  13ml x 1 vial 13ml x 1 vial 13ml x 1 vial 50ml x 2 vials





**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**E.COLI O ANTISERA MONOVALENT**

M12013	<i>E.coli</i> O1	2ml
M12015	<i>E.coli</i> O86a	2ml
M12019	<i>E.coli</i> O128	2ml
M12020	<i>E.coli</i> O44	2ml
M12021	<i>E.coli</i> O55	2ml
M12022	<i>E.coli</i> O125	2ml
M12023	<i>E.coli</i> O126	2ml
M12024	<i>E.coli</i> O146	2ml
M12025	<i>E.coli</i> O166	2ml
M12026	<i>E.coli</i> O18	2ml
M12027	<i>E.coli</i> O114	2ml
M12028	<i>E.coli</i> O142	2ml
M12029	<i>E.coli</i> O151	2ml
M12031	<i>E.coli</i> O158	2ml
M12032	<i>E.coli</i> O6	2ml
M12033	<i>E.coli</i> O27	2ml
M12034	<i>E.coli</i> O78	2ml
M12035	<i>E.coli</i> O148	2ml
M12036	<i>E.coli</i> O159	2ml
M12037	<i>E.coli</i> O168	2ml
M12038	<i>E.coli</i> O20	2ml
M12039	<i>E.coli</i> O25	2ml
M12040	<i>E.coli</i> O63	2ml
M12041	<i>E.coli</i> O153	2ml
M12042	<i>E.coli</i> O167	2ml
M12043	<i>E.coli</i> O8	2ml
M12044	<i>E.coli</i> O15	2ml
M12045	<i>E.coli</i> O115	2ml
M12046	<i>E.coli</i> O169	2ml
M12047	<i>E.coli</i> O28ac	2ml
M12048	<i>E.coli</i> O112ac	2ml
M12049	<i>E.coli</i> O124	2ml
M12050	<i>E.coli</i> O136	2ml
M12051	<i>E.coli</i> O144	2ml
M12052	<i>E.coli</i> O29	2ml
M12053	<i>E.coli</i> O143	2ml
M12054	<i>E.coli</i> O152	2ml
M12055	<i>E.coli</i> O164	2ml

**E.COLI H ANTISERA MONOVALENT**

M12056	<i>E.coli</i> H-2	5ml
M12057	<i>E.coli</i> H-4	5ml
M12058	<i>E.coli</i> H-5	5ml
M12059	<i>E.coli</i> H-6	5ml
M12060	<i>E.coli</i> H-7	5ml
M12061	<i>E.coli</i> H-9	5ml
M12062	<i>E.coli</i> H-10	5ml
M12063	<i>E.coli</i> H-11	5ml
M12064	<i>E.coli</i> H-12	5ml
M12065	<i>E.coli</i> H-16	5ml
M12066	<i>E.coli</i> H-18	5ml
M12067	<i>E.coli</i> H-19	5ml
M12068	<i>E.coli</i> H-20	5ml
M12069	<i>E.coli</i> H-21	5ml
M12070	<i>E.coli</i> H-27	5ml
M12071	<i>E.coli</i> H-28	5ml



**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**E.COLI H ANTISERA MONOVALENT (cont)**

M12072	<i>E.coli</i> H-34	5ml
M12073	<i>E.coli</i> H-40	5ml
M12074	<i>E.coli</i> H-41	5ml
M12075	<i>E.coli</i> H-42	5ml
M12076	<i>E.coli</i> H-45	5ml
M12077	<i>E.coli</i> H-51	5ml

**TOXIGENIC E.COLI PILI ANTISERA**

M11601/NCE	<b>Toxigenic <i>Escherichia coli</i> Pili Antisera Set</b> This set consists of the following K88, K99 and 987P	No CE Mark	5ml x 3
M11602/NCE	<i>E.coli</i> K88	No CE Mark	5ml
M11603/NCE	<i>E.coli</i> K99	No CE Mark	5ml
M11604/NCE	<i>E.coli</i> 987P	No CE Mark	5ml

**HAEMOPHILUS INFLUENZAE ANTISERA**

M11301	<b><i>Haemophilus influenzae</i> Antisera Set</b> This set consists of: Type a, b, c, d, e and f		2ml x 6
	<b><i>Haemophilus influenzae</i> type listed below</b>		
M11302	<i>H.influenzae</i> Type a		2ml
M11304	<i>H.influenzae</i> Type c		2ml
M11305	<i>H.influenzae</i> Type d		2ml
M11306	<i>H.influenzae</i> Type e		2ml
M11307	<i>H.influenzae</i> Type f	No CE Mark	2ml

**KLEBSIELLA CAPSULAR TYPING ANTISERA**

M11201/NCE	<b><i>Klebsiella</i> Capsular Typing Antisera Set</b> This set consists of 6 typing sera. Type 1~6	No CE Mark	2ml x 6
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**LEGIONELLA ANTISERA**

M11701	<b><i>Legionella</i> O-Grouping Antisera Set</b> This set consists of: <i>L.pneumophila</i> 1~6, <i>L.bozemanii</i> , <i>L.dumoffi</i> , <i>L.gormanii</i> and <i>L.micdadei</i>		2ml x 10
	<b><i>Legionella</i> O-Group listed below</b>		
M11702	<i>L.pneumophila</i> Group 1		2ml
M11703	<i>L.pneumophila</i> Group 2		2ml
M11704	<i>L.pneumophila</i> Group 3		2ml
M11705	<i>L.pneumophila</i> Group 4		2ml
M11706	<i>L.pneumophila</i> Group 5		2ml
M11707	<i>L.pneumophila</i> Group 6		2ml
M11708	<i>L.bozemanii</i>		2ml
M11709	<i>L.dumoffi</i>		2ml
M11710	<i>L.gormanii</i>		2ml
M11711	<i>L.micdadei</i>		2ml

**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**LISTERIA ANTISERA**

M14362	<b>Listeria Antisera Set</b> This set consists of 8 O antisera and 4 H antisera. O antisera: O I/II, O I, O IV, O V/VI, O VI, O VII, O VIII and O IX H antisera: H-A, H-AB, H-C and H-D	2ml x 8 vials 5ml x 4 vials
M14379	Listeria O I/II antiserum	2ml
M14386	Listeria O I antiserum	2ml
M14393	Listeria O IV antiserum	2ml
M14409	Listeria O V/VI antiserum	2ml
M14416	Listeria O VI antiserum	2ml
M14423	Listeria O VII antiserum	2ml
M14430	Listeria O VIII antiserum	2ml
M14447	Listeria O IX antiserum	2ml
M14454	Listeria H-A antiserum	5ml
M14461	Listeria H-AB antiserum	5ml
M14478	Listeria H-C antiserum	5ml
M14485	Listeria H-D antiserum	5ml

**PSEUDOMONAS ANTISERA**

M10702/NCE	<b><i>Pseudomonas aeruginosa</i> Antisera Set</b> This set consists of 3 Polyvalent and 14 Monovalent antisera. <b>Polyvalent</b> Polyvalent I: A, C, H, I and L Polyvalent II: B, J, K and M Polyvalent III: D, E, F, G and N <b>Monovalent</b> Type A, B, C, D, E, F, G, H, I, J, K, L, M and N	No CE Mark	2ml x 17
M10704/NCE	<b><i>Pseudomonas aeruginosa</i> Antisera type listed below</b> Polyvalent I: A, C, H, I and L	No CE Mark	2ml
M10705/NCE	Polyvalent II: B, J, K and M	No CE Mark	2ml
M10706/NCE	Polyvalent III: D, E, F, G and N	No CE Mark	2ml
M10707/NCE	<i>Pseudomonas aeruginosa</i> Group A	No CE Mark	2ml
M10712/NCE	<i>Pseudomonas aeruginosa</i> Group B	No CE Mark	2ml
M10708/NCE	<i>Pseudomonas aeruginosa</i> Group C	No CE Mark	2ml
M10716/NCE	<i>Pseudomonas aeruginosa</i> Group D	No CE Mark	2ml
M10717/NCE	<i>Pseudomonas aeruginosa</i> Group E	No CE Mark	2ml
M10718/NCE	<i>Pseudomonas aeruginosa</i> Group F	No CE Mark	2ml
M10719/NCE	<i>Pseudomonas aeruginosa</i> Group G	No CE Mark	2ml
M10709/NCE	<i>Pseudomonas aeruginosa</i> Group H	No CE Mark	2ml
M10710/NCE	<b><i>Pseudomonas aeruginosa</i> Antisera type listed below</b> <i>Pseudomonas aeruginosa</i> Group I	No CE Mark	2ml
M10713/NCE	<i>Pseudomonas aeruginosa</i> Group J	No CE Mark	2ml
M10714/NCE	<i>Pseudomonas aeruginosa</i> Group K	No CE Mark	2ml
M10711/NCE	<i>Pseudomonas aeruginosa</i> Group L	No CE Mark	2ml
M10715/NCE	<i>Pseudomonas aeruginosa</i> Group M	No CE Mark	2ml
M10720/NCE	<i>Pseudomonas aeruginosa</i> Group N	No CE Mark	2ml

**SALMONELLA O ANTISERA - MONOVALENT**

M10315	Salmonella O Factor	O9.46	2ml
M10318	Salmonella O Factor	O1,3,19	2ml
M10319	Salmonella O Factor	O11	2ml
M10322	Salmonella O Factor	O16	2ml
M10323	Salmonella O Factor	O18	2ml
M10324	Salmonella O Factor	O21	2ml
M10325	Salmonella O Factor	O35	2ml



**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**SALMONELLA H ANTISERA - MONOVALENT**

M10335	Salmonella H Factor	L	2ml
M10337	Salmonella H Factor	y	2ml
M10338	Salmonella H Factor	e,n	2ml
M10340	Salmonella H Factor	v	2ml
M10341	Salmonella H Factor	w	2ml
M10342	Salmonella H Factor	z13	2ml
M10343	Salmonella H Factor	z28	2ml
M10347	Salmonella H Factor	7	2ml
M10348	Salmonella H Factor	z6	2ml
M10370	Salmonella H Factor	u	2ml
M10372	Salmonella H Factor	z23	2ml
M10373	Salmonella H Factor	z24	2ml
M10376	Salmonella H Factor	x	2ml
M10377	Salmonella H Factor	z15	2ml
M10374	Salmonella H Factor	z32	2ml
M10378	Salmonella H Factor	z	2ml
M10379	Salmonella H Factor	z4	2ml
M10380	Salmonella H Factor	z10	2ml
M10381	Salmonella H Factor	z29	2ml
M91882/NCE	Salmonella H Factor	g,p	No CE Mark 5ml
M10303	<b>Salmonella Antisera Set 1</b> This set consists of 17 O-grouping and Vi sera Polyvalent O: O2, O4, O7, O8, O9, O9, 46, O3,10 & O1, 3, 19 Polyvalent O1: O11, O13, O6, O14, O16, O18, O21 and O35 Monovalent: O2, O4, O7, O8, O9, O9 ,46, O3, 10, O1, 3, 19, O11, O13, O6, 14, O16, O18, 21 and O35, Vi serum		2ml x 18
M10304	<b>Salmonella Antisera Set 2</b> This set consists of 17 H antisera. a, b, c, d, e, h, G, i, k, L, r, y, e,n, l, z, z4, z10 and z29		5ml x 17
M10386	<b>Salmonella Antisera Set 3</b> This set consists of four H-L Monovalent sera:- v, w, z13 and z28		5ml x 4
M10387	<b>Salmonella Antisera Set 4</b> This set consists of five H-1 Monovalent sera 2, 5, 6, 7 and z6		5ml x 5
M10388	<b>Salmonella Antisera Set 5</b> This set consists of seven H-G Monovalent sera:- f, m, p, q, s, t and u		5ml x 7
M10389	<b>Salmonella Antisera Set 6</b> This set consists of three H-z4 and two H-e,n. Monovalent sera. z23, z24, z32, x and z15		5ml x 5
M10390	<b>Salmonella Antisera Set 7</b> This set consists of the following. O-grouping sera: O2 and O9 H-sera: a and d Vi serum		2ml x 2 5ml x 2 2ml x 1

**SHIGELLA ANTISERA - MONOVALENT**

M10117	<i>Shigella dysenteriae</i>	Type 2	2ml
M10118	<i>Shigella dysenteriae</i>	Type 3	2ml
M10119	<i>Shigella dysenteriae</i>	Type 4	2ml
M10120	<i>Shigella dysenteriae</i>	Type 5	2ml
M10121	<i>Shigella dysenteriae</i>	Type 6	2ml

**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**SHIGELLA ANTISERA - MONOVALENT (cont)**

M10122	<i>Shigella dysenteriae</i>	Type 7	2ml
M10123	<i>Shigella dysenteriae</i>	Type 8	2ml
M10124	<i>Shigella dysenteriae</i>	Type 9	2ml
M10125	<i>Shigella dysenteriae</i>	Type 10	2ml
M10152	<i>Shigella dysenteriae</i>	Type 11	2ml
M10153	<i>Shigella dysenteriae</i>	Type 12	2ml
M10128	<i>Shigella flexneri</i>	Type III	2ml
M10129	<i>Shigella flexneri</i>	Type IV	2ml
M10132	<i>Shigella flexneri</i>	Group (3)4	2ml
M10133	<i>Shigella flexneri</i>	Group 6	2ml
M10134	<i>Shigella flexneri</i>	Group 7 (8)	2ml
M10135	<i>Shigella boydii</i>	Type 1	2ml
M10137	<i>Shigella boydii</i>	Type 3	2ml
M10138	<i>Shigella boydii</i>	Type 4	2ml
M10139	<i>Shigella boydii</i>	Type 5	2ml
M10140	<i>Shigella boydii</i>	Type 6	2ml
M10141	<i>Shigella boydii</i>	Type 7	2ml
M10142	<i>Shigella boydii</i>	Type 8	2ml
M10143	<i>Shigella boydii</i>	Type 9	2ml
M10144	<i>Shigella boydii</i>	Type 10	2ml
M10145	<i>Shigella boydii</i>	Type 11	2ml
M10146	<i>Shigella boydii</i>	Type 12	2ml
M10147	<i>Shigella boydii</i>	Type 13	2ml
M10148	<i>Shigella boydii</i>	Type 14	2ml
M10149	<i>Shigella boydii</i>	Type 15	2ml
M10155	<i>Shigella boydii</i>	Type 16	2ml
M10156	<i>Shigella boydii</i>	Type 17	2ml
M10157	<i>Shigella boydii</i>	Type 18	2ml
M10104	<b>Shigella Antisera Set 1</b>		2ml x 49
	This set consists of 8 Polyvalent and 41 Monovalents.		
	<b>Polyvalent serum</b>		
	Polyvalent A: <i>S.dysenteriae</i> Type 1, 2, 3, 4, 5, 6 & 7		
	Polyvalent A1: <i>S.dysenteriae</i> Type 8, 9, 10, 11 & 12		
	Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI & Group (3) 4, 6 and 7 (8)		
	Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7		
	Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11		
	Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15		
	Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18		
	Polyvalent D: <i>S.sonnei</i> Phase I and Phase II		
	<b>Monovalent serum</b>		
	All individual types and groups constituting above polyvalent sera.		
M10105	<b>Shigella Antisera Set 2</b>		2ml x 19
	This set consists of 8 Polyvalents and 11 Monovalents.		
	<b>Polyvalent serum</b>		
	Polyvalent A: <i>S.dysenteriae</i> Type 1, 2, 3, 4, 5, 6 & 7		
	Polyvalent A1: <i>S.dysenteriae</i> Type 8, 9, 10, 11 & 12		
	Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI and Group (3) 4, 6 and 7 (8)		
	Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7		
	Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11		
	Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15		
	Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18		
	Polyvalent D: <i>S.sonnei</i> Phase I and Phase II		
	<b>Monovalent serum</b>		
	<i>S.flexneri</i> : type I, II, III, IV, V, VI and Group: (3) 4, 6 and 7 (8).		
	<i>S.sonnei</i> : Phase I and Phase II.		



**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**SHIGELLA ANTISERA SETS (cont)**

M10106	<p><b>Shigella Antisera Set 3</b>                  Polyvalent A: <i>S.dysenteriae</i> Type 1, 2,3, 4, 5, 6, &amp; 7                  Polyvalent A1: <i>S. dysenteriae</i> Type 8, 9, 10, 11 &amp; 12                  Polyvalent B; <i>S.flexneri</i> Type I, II, III, IV, V, VI and Group (3) 4, 6 and 7 (8)                  Polyvalent C: <i>S.boydii</i> Type 1, 2, 3, 4, 5, 6 and 7                  Polyvalent C1: <i>S.boydii</i> Type 8, 9, 10 and 11                  Polyvalent C2: <i>S.boydii</i> Type 12, 13, 14 and 15                  Polyvalent C3: <i>S.boydii</i> Type 16, 17 and 18                  Polyvalent D: <i>S.sonnei</i> Phase I and Phase II</p>	2ml x 8
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**STAPHYLOCOCCUS ANTISERA**

M10801	<p><b>Staphylococcal Coagulase Typing Sera Set</b>                  This set consists of 8 typing sera.                  Types: I, II, III, IV, V, VI, VII, and VIII</p>	5ml x 8
	<b>Staphylococcal coagulase type listed below</b>	
M10802	<i>Staphylococcal coagulase</i> type I	5ml
M10803	<i>Staphylococcal coagulase</i> type II	5ml
M10804	<i>Staphylococcal coagulase</i> type III	5ml
M10805	<i>Staphylococcal coagulase</i> type IV	5ml
M10806	<i>Staphylococcal coagulase</i> type V	5ml
M10807	<i>Staphylococcal coagulase</i> type VI	5ml
M10808	<i>Staphylococcal coagulase</i> type VII	5ml
M10809	<i>Staphylococcal coagulase</i> type VIII	5ml

**HAEMOLYTIC STREPTOCOCCUS GROUP-A T-TYPING**

	<p><b>Haemolytic Streptococcus Group-A T-Typing</b>                  Sera type listed below</p>		
M10516/NCE	Group A Streptococcus T-2	No CE Mark	2ml
M10570	<p><b>Haemolytic Streptococcus Group-B Typing Sera Set</b>                  This set consists of Antisera types: Ia, Ib, II, III, IV and V</p>		2ml x 6
	<b>Haemolytic Streptococcus Group-B Typing</b>		
	Sera type listed below		
M10540	Group B Streptococcus Ia		2ml
M10541	Group B Streptococcus Ib		2ml
M10542	Group B Streptococcus II		2ml
M10543	Group B Streptococcus III		2ml
M10544	Group B Streptococcus IV		2ml
M10545	Group B Streptococcus V		2ml
M93350	Group B Streptococcus VI		2ml
M93374	Group B Streptococcus VII		2ml
M93367	Group B Streptococcus VIII		2ml
M20209	<p><b>Auxiliary reagents for Haemolytic Streptococcus typing</b>                  Swine pancreas extract                  pH correction solution                  Phenol Red solution</p>		5ml x 4 5ml x 2 5ml x 1

**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**STREPTOCOCCUS PNEUMONIAE ANTISERA**

M00747	<b>Streptococcus pneumoniae Antisera typing set</b> This kit consists of 8 polyvalent and 39 monovalent antisera		2ml x 47
	<b>Streptococcus pneumoniae POLYVALENT typing Antisera</b>		
M15253	<i>Streptococcus pneumoniae</i> Polyvalent 1 antiserum: contains 1,2,3,4 and 5		2ml
M15260	2 antiserum: contains 6,8,9 and 10		2ml
M15277	3 antiserum: contains 11,12,14,15 and 16		2ml
M15284	4 antiserum: contains 17,18,21 and 22		2ml
M15291	5 antiserum: contains 20,29,31,33,34,35 and 47		2ml
M15307	6 antiserum: contains 23,25,28,41 and 46		2ml
M15314	7 antiserum: contains 27,32,36,38 and 39		2ml
M15321	8 antiserum: contains 7,19,24 and 40		2ml
M15338	<i>Streptococcus pneumoniae</i>	type 1 antiserum	2ml
M15345	<i>Streptococcus pneumoniae</i>	type 2 antiserum	2ml
M15352	<i>Streptococcus pneumoniae</i>	type 3 antiserum	2ml
M15369	<i>Streptococcus pneumoniae</i>	type 4 antiserum	2ml
M15376	<i>Streptococcus pneumoniae</i>	type 5 antiserum	2ml
M15383	<i>Streptococcus pneumoniae</i>	type 6 antiserum	2ml
M15390	<i>Streptococcus pneumoniae</i>	type 7 antiserum	2ml
M15406	<i>Streptococcus pneumoniae</i>	type 8 antiserum	2ml
M15413	<i>Streptococcus pneumoniae</i>	type 9 antiserum	2ml
M15420	<i>Streptococcus pneumoniae</i>	type 10 antiserum	2ml
M15437	<i>Streptococcus pneumoniae</i>	type 11 antiserum	2ml
M15444	<i>Streptococcus pneumoniae</i>	type 12 antiserum	2ml
M15451	<i>Streptococcus pneumoniae</i>	type 14 antiserum	2ml
M15468	<i>Streptococcus pneumoniae</i>	type 15 antiserum	2ml
M15475	<i>Streptococcus pneumoniae</i>	type 16 antiserum	2ml
M15482	<i>Streptococcus pneumoniae</i>	type 17 antiserum	2ml
M15499	<i>Streptococcus pneumoniae</i>	type 18 antiserum	2ml
M15505	<i>Streptococcus pneumoniae</i>	type 19 antiserum	2ml
M15512	<i>Streptococcus pneumoniae</i>	type 20 antiserum	2ml
M15529	<i>Streptococcus pneumoniae</i>	type 21 antiserum	2ml
M15536	<i>Streptococcus pneumoniae</i>	type 22 antiserum	2ml
M15543	<i>Streptococcus pneumoniae</i>	type 23 antiserum	2ml
M15550	<i>Streptococcus pneumoniae</i>	type 24 antiserum	2ml
M15567	<i>Streptococcus pneumoniae</i>	type 25 antiserum	2ml
M15574	<i>Streptococcus pneumoniae</i>	type 26 antiserum	2ml
M15581	<i>Streptococcus pneumoniae</i>	type 28 antiserum	2ml
M15598	<i>Streptococcus pneumoniae</i>	type 29 antiserum	2ml
M15604	<i>Streptococcus pneumoniae</i>	type 31 antiserum	2ml
M15611	<i>Streptococcus pneumoniae</i>	type 32 antiserum	2ml
M15628	<i>Streptococcus pneumoniae</i>	type 33 antiserum	2ml
M15635	<i>Streptococcus pneumoniae</i>	type 34 antiserum	2ml
M15642	<i>Streptococcus pneumoniae</i>	type 35 antiserum	2ml
M15659	<i>Streptococcus pneumoniae</i>	type 36 antiserum	2ml
M15666	<i>Streptococcus pneumoniae</i>	type 38 antiserum	2ml
M15673	<i>Streptococcus pneumoniae</i>	type 39 antiserum	2ml
M15680	<i>Streptococcus pneumoniae</i>	type 40 antiserum	2ml
M15697	<i>Streptococcus pneumoniae</i>	type 41 antiserum	2ml
M15703	<i>Streptococcus pneumoniae</i>	type 46 antiserum	2ml
M15710	<i>Streptococcus pneumoniae</i>	type 47 antiserum	2ml

**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**VIBRIO PARAHAEMOLYTICUS ANTISERA**

M10495/NCE	<p><b>Vibrio parahaemolyticus K-typing Antisera Set</b> This set consists of 9 Polyvalent and 65 Monovalent K-Antisera.</p> <p><b>Polyvalent Antisera</b> Polyvalent KI: 1, 3, 4, 5, 6, 7 and 8 Polyvalent KII: 9, 10, 11, 12, 13, 15 and 17 Polyvalent KIII: 18, 19, 20, 21, 22, 23 and 24 Polyvalent KIV: 25, 26, 28, 29, 30, 31 and 32 Polyvalent KV: 33, 34, 36, 37, 38, 39 and 40 Polyvalent KVI: 41, 42, 43, 44, 45, 46 and 47 Polyvalent KVII: 48, 49, 50, 51, 52, 53 and 54 Polyvalent KVIII: 55, 56, 57, 58, 59, 60 and 61 Polyvalent KIX: 63, 64, 65, 66, 67, 68 and 69</p> <p><b>Monovalent</b> K1~K71 except K2, K14, K16, K27, K35 and K62</p>	No CE Mark	2ml x 74
M10402/NCE	<p><b>Vibrio parahaemolyticus O-grouping Antisera Set</b> This set consists of 11 O-grouping sera. 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and 11</p>	No CE Mark	2ml x 11
	<p><b>Vibrio parahaemolyticus Antisera type listed below</b></p>		
M10405/NCE	<i>V.parahaemolyticus</i> Polyvalent KI contains types 1, 3, 4, 5, 6, 7, & 8	No CE Mark	2ml
M10406/NCE	<i>V.parahaemolyticus</i> Polyvalent KII contains types 9, 10, 11, 12, 13, 15 and 17	No CE Mark	2ml
M10407/NCE	<i>V.parahaemolyticus</i> Polyvalent KIII contains types 18, 19, 20, 21, 22, 23 and 24	No CE Mark	2ml
M10408/NCE	<i>V.parahaemolyticus</i> Polyvalent KIV contains types 25, 26, 28, 29, 30, 31 and 32	No CE Mark	2ml
M10409/NCE	<i>V.parahaemolyticus</i> Polyvalent KV contains types 33, 34, 36, 37, 38, 39 and 40	No CE Mark	2ml
M10410/NCE	<i>V.parahaemolyticus</i> Polyvalent KVI contains types 41, 42, 43, 44, 45, 46, and 47	No CE Mark	2ml
M10411/NCE	<i>V.parahaemolyticus</i> Polyvalent KVII contains types 48, 49, 50, 51, 52, 53 and 54	No CE Mark	2ml
M10412/NCE	<i>V.parahaemolyticus</i> Polyvalent KVIII contains types 55, 56, 57, 58, 59, 60 and 61	No CE Mark	2ml
M10482/NCE	<i>V.parahaemolyticus</i> Polyvalent KIX contains types 63, 64, 65, 66, 67, 68 and 69	No CE Mark	2ml
M10413/NCE	<i>V.parahaemolyticus</i> K1	No CE Mark	2ml
M10414/NCE	<i>V.parahaemolyticus</i> K3	No CE Mark	2ml
M10415/NCE	<i>V.parahaemolyticus</i> K4	No CE Mark	2ml
M10416/NCE	<i>V.parahaemolyticus</i> K5	No CE Mark	2ml
M10417/NCE	<i>V.parahaemolyticus</i> K6	No CE Mark	2ml
M10418/NCE	<i>V.parahaemolyticus</i> K7	No CE Mark	2ml
M10419/NCE	<i>V.parahaemolyticus</i> K8	No CE Mark	2ml
M10420/NCE	<i>V.parahaemolyticus</i> K9	No CE Mark	2ml
M10421/NCE	<i>V.parahaemolyticus</i> K10	No CE Mark	2ml
M10422/NCE	<i>V.parahaemolyticus</i> K11	No CE Mark	2ml
M10423/NCE	<i>V.parahaemolyticus</i> K12	No CE Mark	2ml
M10424/NCE	<i>V.parahaemolyticus</i> K13	No CE Mark	2ml
M10425/NCE	<i>V.parahaemolyticus</i> K15	No CE Mark	2ml
M10426/NCE	<i>V.parahaemolyticus</i> K17	No CE Mark	2ml
M10427/NCE	<i>V.parahaemolyticus</i> K18	No CE Mark	2ml
M10428/NCE	<i>V.parahaemolyticus</i> K19	No CE Mark	2ml
M10429/NCE	<i>V.parahaemolyticus</i> K20	No CE Mark	2ml
M10430/NCE	<i>V.parahaemolyticus</i> K21	No CE Mark	2ml
M10431/NCE	<i>V.parahaemolyticus</i> K22	No CE Mark	2ml
M10432/NCE	<i>V.parahaemolyticus</i> K23	No CE Mark	2ml
M10433/NCE	<i>V.parahaemolyticus</i> K24	No CE Mark	2ml
M10434/NCE	<i>V.parahaemolyticus</i> K25	No CE Mark	2ml
M10435/NCE	<i>V.parahaemolyticus</i> K26	No CE Mark	2ml



**MAST ASSURE™ ANTISERA - SUPPLEMENTARY LIST**

Lead time 8 weeks

**VIBRIO PARAHAEMOLYTICUS ANTISERA (cont)**

M10436/NCE	<i>V.parahaemolyticus</i> K28	No CE Mark	2ml
M10437/NCE	<i>V.parahaemolyticus</i> K29	No CE Mark	2ml
M10438/NCE	<i>V.parahaemolyticus</i> K30	No CE Mark	2ml
M10439/NCE	<i>V.parahaemolyticus</i> K31	No CE Mark	2ml
M10440/NCE	<i>V.parahaemolyticus</i> K32	No CE Mark	2ml
M10442/NCE	<i>V.parahaemolyticus</i> K34	No CE Mark	2ml
M10445/NCE	<i>V.parahaemolyticus</i> K38	No CE Mark	2ml
M10448/NCE	<i>V.parahaemolyticus</i> K41	No CE Mark	2ml
M10449/NCE	<i>V.parahaemolyticus</i> K42	No CE Mark	2ml
M10450/NCE	<i>V.parahaemolyticus</i> K43	No CE Mark	2ml
M10451/NCE	<i>V.parahaemolyticus</i> K44	No CE Mark	2ml
M10452/NCE	<i>V.parahaemolyticus</i> K45	No CE Mark	2ml
M10453/NCE	<i>V.parahaemolyticus</i> K46	No CE Mark	2ml
M10454/NCE	<i>V.parahaemolyticus</i> K47	No CE Mark	2ml
M10455/NCE	<i>V.parahaemolyticus</i> K48	No CE Mark	2ml
M10456/NCE	<i>V.parahaemolyticus</i> K49	No CE Mark	2ml
M10457/NCE	<i>V.parahaemolyticus</i> K50	No CE Mark	2ml
M10458/NCE	<i>V.parahaemolyticus</i> K51	No CE Mark	2ml
M10459/NCE	<i>V.parahaemolyticus</i> K52	No CE Mark	2ml
M10460/NCE	<i>V.parahaemolyticus</i> K53	No CE Mark	2ml
M10461/NCE	<i>V.parahaemolyticus</i> K54	No CE Mark	2ml
M10462/NCE	<i>V.parahaemolyticus</i> K55	No CE Mark	2ml
M10463/NCE	<i>V.parahaemolyticus</i> K56	No CE Mark	2ml
M10464/NCE	<i>V.parahaemolyticus</i> K57	No CE Mark	2ml
M10465/NCE	<i>V.parahaemolyticus</i> K58	No CE Mark	2ml
M10466/NCE	<i>V.parahaemolyticus</i> K59	No CE Mark	2ml
M10467/NCE	<i>V.parahaemolyticus</i> K60	No CE Mark	2ml
M10479/NCE	<i>V.parahaemolyticus</i> K61	No CE Mark	2ml
M10480/NCE	<i>V.parahaemolyticus</i> K63	No CE Mark	2ml
M10488/NCE	<i>V.parahaemolyticus</i> K66	No CE Mark	2ml
M10489/NCE	<i>V.parahaemolyticus</i> K67	No CE Mark	2ml
M10490/NCE	<i>V.parahaemolyticus</i> K68	No CE Mark	2ml
M10496/NCE	<i>V.parahaemolyticus</i> K71	No CE Mark	2ml
M10468/NCE	<i>V.parahaemolyticus</i> O1	No CE Mark	2ml
M10469/NCE	<i>V.parahaemolyticus</i> O2	No CE Mark	2ml
M10470/NCE	<i>V.parahaemolyticus</i> O3	No CE Mark	2ml
M10471/NCE	<i>V.parahaemolyticus</i> O4	No CE Mark	2ml
M10472/NCE	<i>V.parahaemolyticus</i> O5	No CE Mark	2ml



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