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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	GMDN code and description
Various MS--	MAST® SELECTATAB – supplements for use in culture media.	Self certification Annex III excluding section 6	GMDN code 58556 GMDN Description - Culture medium antimicrobial supplement IVD
Various SV--	MAST® SELECTAVIAL – supplements for use in culture media and other applications.	Self certification Annex III excluding section 6	GMDN code 58556 GMDN Description - Culture medium antimicrobial supplement IVD

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 C Winstanley Date: 01st May 2022

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



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: Selective supplements

Annex – list of MAST® Culture Medium supplements

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
1	MS25	Actinomycete Selectatab	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Actinomycete Selection
2	SV38	Brucella Selectavial	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Brucella
3	MS22	Burkholderia cepacia Selectatab	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Burkholderia cepacia
4	SV22	Burkholderia cepacia Selectavial	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Burkholderia cepacia
5	MS26	Camp Selectatab (Modified Butzler)	10 Tablets-1 Tablet per 500ml	MAST® SELECTATAB	Cultural Media Supplement - Campylobacter Selection
6	MS18	Camp Selectatab (Preston Blood Free)	25 Tablets-1 Tablet per 250ml	MAST® SELECTATAB	Cultural Media Supplement - Campylobacter Selection
7	SV18	Camp Selectavial (Preston Blood Free)	10 Vials-1 Vial per 1000ml	MAST® SELECTAVIAL	Cultural Media Supplement - Campylobacter Selection
8	MS3	Camp Selectatab (Skirrow)	25 Tablets-1 Tablet per 250ml	MAST® SELECTATAB	Cultural Media Supplement - Campylobacter Selection
9	SV3	Camp Selectavial (Skirrow)	10 Vials-1 Vial per 1000ml	MAST® SELECTAVIAL	Cultural Media Supplement - Campylobacter Selection
10	SV61	Campylobacter Growth Supplement	10 Vials-1 Vial per 1125ml	MAST® SELECTAVIAL	Cultural Media Supplement - Campylobacter Selective Enrichment
11	SV59	Campylobacter Selective Supplement	10 Vials-1 Vial per 1125ml	MAST® SELECTAVIAL	Cultural Media Supplement - Campylobacter Selective Enrichment
12	SV54	Chloramphenicol Selectavial	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Yeast & Mould Isolation
13	SV23	Clostridium difficile Selectavial	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Clostridium difficile Selection



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
14	SV16	G.C. Growth Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - G.C. Selection
15	SV20	G.C. Selectavial (L.C.A.T.)	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - G.C. Selection
16	SV6	G.C. Selectavial (V.C.N.T.)	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - G.C. Selection
17	SV5	G.C. Selectavial (V.C.T.)	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - G.C. Selection
18	MS15	Gardnerella Selectatab	25 Tablets-1 Tablet per 250ml	MAST® SELECTATAB	Cultural Media Supplement - Gardnerella Selection
19	SV94	GVPN Selectavial	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Legionella Selection
20	MS27	Haemophilus Selectatab (Bacitracin)	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Haemophilus Selection
21	SV27	Haemophilus Selectavial (Bacitracin)	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Haemophilus Selection
22	SV35	Legionella Growth Supplement (L-CYS)	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Legionella Enrichment
23	SV36	Legionella Selectavial (MWY)	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Legionella Selection
24	SV37	Legionella Selectavial (PNV)	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media Supplement - Legionella Selection
25	SV33	Listeria Selectavial (Oxford) Formula	10 Vials-1 Vial per 500ml	MAST® SELECTAVIAL	Cultural Media & Supplements - Listeria Selection
26	MS29	MRSA Selectatab (Oxacillin)	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Staphylococcus aureus Isolation (Methicillin resistant)
27	MS24	Mycobacteria Selectatab (Kirchner)	10 Tablets-1 Tablet per 500ml	MAST® SELECTATAB	Cultural Media Supplement - Staphylococcus aureus Isolation (Methicillin resistant)
28	SV82	NAD Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Haemophilus Selection
29	SV9	Nalidixic Acid Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Anaerobe Isolation



Serial No.	Device ID Number	Product Description	Pack Size	Brand Name	Intended purpose of the medical device type
30	MS8	Neomycin Selectatab	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Anaerobe Isolation
31	MS8A	Neomycin Selectatab	10 Tablets-1 Tablet per 500ml	MAST® SELECTATAB	Cultural Media Supplement - Anaerobe Isolation
32	SV8	Neomycin Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Anaerobe Isolation
33	MS2	P.N.P.G. Selectatab	25 Tablets-1 Tablet per 100ml	MAST® SELECTATAB	Cultural Media Supplement - Proteus-Inhibition of Swarming
34	MS2A	P.N.P.G. Selectatab	10 Tablets-1 Tablet per 500ml	MAST® SELECTATAB	Cultural Media Supplement - Proteus-Inhibition of Swarming
35	SV2	P.N.P.G. Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Proteus-Inhibition of Swarming
37	SV11	Staph/Strep Selectavial	10 Vials-1 Vial per 1 Litre	MAST® SELECTAVIAL	Cultural Media Supplement - Staphylococcus/Streptococcus Selection
38	MS12	Streptococcus Selectatab	25 Tablets-1 Tablet per 250ml	MAST® SELECTATAB	Cultural Media Supplement - Staphylococcus Selection
39	MS19	Yersinia Selectatab	25 Tablets-1 Tablet per 250ml	MAST® SELECTATAB	Cultural Media & Supplements - Yersinia Selection