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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 (DM---)	MAST® Dehydrated culture media – Powdered product formulations for use in microbial culture media.	Self certification Annex III excluding section 6	1401010100, 1401010200, 1403010100 (Codes registered - 24/03/2003) GMDN codes 30630, 30660

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

Declaration made by Christine Winstanley

Date: 26 May 2022

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

Document valid till: 26th May 2025



European In Vitro Diagnostic Medical Directive 98/79/EC, Annex III – General IVD

EC DECLARATION OF CONFORMITY- Self-Certification (Annex III excluding section 6) – General IVD

Product Names: Mast Dehydrated Culture Media

Serial No.	Device ID Number	Product Description	Pack Size	EDMS/GMDN code	Brand Name	Intended purpose of the medical device type
1	DM095D	Baird-Parker Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
2	DM494D	Buffered Peptone Water	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
3	DM494E	Buffered Peptone Water	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
4	DM269D	Buffered Rappaport Vassiliadis Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
5	DM253D	Burkholderia cepacia Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
6	DM110A	C.L.E.D. Medium	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
7	DM110B	C.L.E.D. Medium	10x500ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
8	DM110D	C.L.E.D. Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
9	DM111D	C.L.E.D. with Andrade's Indicator	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
10	DM111E	C.L.E.D. with Andrade's Indicator	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
11	DM119E	Cooked Meat Granules	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
12	DM130D	D.C.A. (Hynes)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
13	DM215B	D.S.T. Agar (Sulphonamide Antagonist Free)	10x 500ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
14	DM215D	D.S.T. Agar (Sulphonamide Antagonist Free)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
15	DM132D	DNase Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
16	DM133D	Eosin Methylene Blue Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
17	DM136D	G.C. Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
18	DM134D	Hektoen Enteric Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
19	DM134E	Hektoen Enteric Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
20	DM146D	Kimmig Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
21	DM137D	Kligler's Iron Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
22	DM138-1D	Kohn's No 1 Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
23	DM258D	Legionella BCYE Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
24	DM440D	M.S.R.V. (Salmonella) Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
25	DM140D	MacConkey Agar (without salt)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
26	DM140E	MacConkey Agar (without salt)	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN code	Brand Name	Intended purpose of the medical device type
27	DM141D	MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
28	DM141E	MacConkey Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
29	DM142D	MacConkey Agar No.2	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
30	DM143D	MacConkey Agar No.3	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
31	DM143E	MacConkey Agar No.3	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
32	DM150D	MacConkey Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
33	DM160D	Mannitol Salt Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
34	DM170B	Mueller Hinton Agar	10x200ml sachets	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
35	DM170D	Mueller Hinton Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
36	DM170E	Mueller Hinton Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
37	DM171D	Mueller Hinton Broth	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
38	DM171N	Mueller Hinton Broth	20Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
39	DM195D	Plate Count Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
40	DM251D	Preston Blood Free Campylobacter Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
41	DM205D	S.S. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media



Serial No.	Device ID Number	Product Description	Pack Size	EMDS/GMDN Code	Brand Name	Intended purpose of the medical device type
42	DM205E	S.S. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
43	DM211D	Simmons Citrate Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
44	DM491D	Sorbitol MacConkey Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
45	DM218D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
46	D401D	T.C.B.S. Cholera Medium	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
47	DM219S	Tetrathionate Broth	460g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
48	DM221D	Thioglycollate Broth USP	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
49	DM224D	Triple Sugar Iron Agar (TSI)	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
50	DM228D	Urea Agar Base	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
51	DM228S	Urea Solution (40% v/v)	10 x10ml	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
52	DM480D	Violet Red Bile (Lactose) Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
53	DM235D	Wilkins Chalgren Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
54	DM230D	X.L.D. Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
55	DM230E	X.L.D. Agar	5Kg	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media
56	DM496D	Yeast Extract Agar	500g	EDMS - 1401010100 GMDN - 30630	Dehydrated culture media and accessories	Cultural Media & Supplements - Clinical & Industrial Culture Media

IVD solutions through partnership



**Mast
Group**

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

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

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

Holds Certificate Number:

FM 724380

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

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



For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 1994-06-14

Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11

Expiry Date: 2024-05-31



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Certificate No: FM 724380

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



Original Registration Date: 1994-06-14
Latest Revision Date: 2021-12-03

Effective Date: 2021-11-11
Expiry Date: 2024-05-31

Certificate of Registration

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

This is to certify that:

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

Holds Certificate Number:

MD 724379

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

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



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31

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Certificate No: **MD 724379**

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



Original Registration Date: 2020-10-07

Latest Revision Date: 2021-11-28

Effective Date: 2021-06-01

Expiry Date: 2024-05-31



SRL SANMEDICO
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Moldova

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TO WHOM IT MAY CONCERN

LETTER OF AUTHORISATION

This letter is to confirm, SRL SANMEDICO of address A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova is authorised to register products, present proposals, offer quotations and accept orders and to participate in tenders as required for Mast Group Limited products.

The undersigned herewith states that the above is true and correct.

Yours faithfully,

Susan Thomson

Bootle UK

December 9th 2021

International business Manager, on behalf of Mast Group

