



Mast Group Ltd.
 Mast House
 Derby Road
 Bootle
 Merseyside L20 1EA
 United Kingdom
 Tel. +44 (0)151 933 7277
 Fax +44 (0)151 944 1332
 www.mastgrp.com


EC DECLARATION OF CONFORMITY

We hereby declare that the devices described below comply with those provisions which apply to them of the European Directive 98/79/EC on *in vitro* diagnostic medical devices, as set out in UK Statutory Instrument 2002 No. 618 "The Medical Device Regulations."

This declaration is valid for the IVD medical devices described below which are placed on the market by ourselves on or after the date hereof and which bear the CE mark. It is also valid for all the IVD medical devices described below which are manufactured by us and placed on the market on or after the date hereof by third parties with our consent and which bear the CE mark. All supporting documents relating to this declaration are retained at the manufacturer's premises.

Product code	Product description	IVD Directive classification	EDMS code
Various (M-----)	MAST ASSURE™ Salmonella Antisera – for serological identification and epidemiological typing with polyvalent and monovalent O (somatic) and H (flagellar) typing antisera.	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003)

Standards applied: EN ISO 13485:2012, ISO 9001:2008, EN ISO 14971:2012, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2012, EN ISO 15223-2:2010.

Declaration made by  Date: 4 January 2017

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

Document valid till: 31 December 2020



**Product Names:
MAST ASSURE™ Salmonella Antisera - for Serological identification and epidemiological typing of bacteria**

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	Intended 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	Intended 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.

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
65	M10303	18x 2ml	MAST ASSURE Salmonella Antiserum Set 1. This set consists of 17 O-grouping and Vi sera	Liquid stable antiserum for the determination of O antigens for the serological identification of salmonellae by slide agglutination.
66	M10304	17x 5ml	MAST ASSURE Salmonella Antiserum Set 2. This set consists of 17 H antisera	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
67	M10386	4x 5ml	MAST ASSURE Salmonella Antiserum Set 3. This set consists of four H-L Monovalent sera.	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
62	M10387	5x 5ml	MAST ASSURE Salmonella Antiserum Set 4. This set consists of five H-1 Monovalent sera 2, 5, 6, 7 & z6.	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
69	M10388	7x 5ml	MAST ASSURE Salmonella Antiserum Set 5. This set consists of seven H-G Monovalent sera.	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
70	M10389	5x 5ml	MAST ASSURE Salmonella Antiserum Set 6. This set consists of three H-z4 and two H-e ₁ n monovalent sera.	Liquid stable antiserum for the determination of H antigens for the serological identification of salmonellae by slide and tube agglutination.
71	M10389	3x 2ml + 2x 5ml	MAST ASSURE Salmonella Antiserum Set 7. This set consists of O2, O9, H-a, H-d and Vi monovalent sera	Liquid stable antiserum for the determination of O and H antigens for the serological identification of salmonellae by slide and tube agglutination.

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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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.