



Mast Group Ltd.  
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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/ 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<br>(code registered - 24/03/2003)<br><br>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. |

# 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



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Certificate No: FM 724380

| Location   | Registered Activities   |
|--|---|
| Mast Group Ltd<br>Mast House, Derby Road<br>Bootle<br>Liverpool<br>L20 1EA<br>United Kingdom     | Design, manufacture and supply of in-vitro diagnostic devices and associated services.  |
| Mast Group Ltd<br>Atlantic House, Derby Road<br>Bootle<br>Liverpool<br>L20 1EA<br>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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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

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Certificate No: **MD 724379**

| Location   | Registered Activities   |
|--|---|
| Mast Group Ltd<br>Mast House, Derby Road<br>Bootle<br>Liverpool<br>L20 1EA<br>United Kingdom     | Design, manufacture and supply of in-vitro diagnostic devices for clinical microbiology and molecular biology and bacteriological media |
| Mast Group Ltd<br>Atlantic House, Derby Road<br>Bootle<br>Liverpool<br>L20 1EA<br>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

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A Member of the BSI Group of Companies.





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United Kingdom

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[www.mast-group.com](http://www.mast-group.com)

**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,

A handwritten signature in black ink, appearing to read "Susan Thomson".

Susan Thomson

Bootle UK

December 9th 2021

International business Manager, on behalf of Mast Group

