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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-----)	MAST® ASSURE Salmonella Antisera – 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 C Winstanley Date: 26th May 2022

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

Document valid till: 26th May 2025


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**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.



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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.



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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.



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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.



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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.