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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 (M-----)	MAST® ASSURE Escherichia coli 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) GMDN code 37727

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



**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 Escherichia coli Antisera - for Serological identification and epidemiological typing of bacteria

Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
1	M12005	2ml	MAST® ASSURE Escherichia Coli POLY D1 (O1, O26, O86a, O111, O119, O127a, O128)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
2	M12006	2ml	MAST® ASSURE Escherichia Coli POLY D2 (O44, O55, O125, O126, O146, O166)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
3	M12007	2ml	MAST® ASSURE Escherichia Coli POLY D3 (O18, O114, O142, O151, O157, O158)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
4	M12008	2ml	MAST® ASSURE Escherichia Coli POLY D4 (O6, O27, O78, O148, O159, O168)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
5	M12009	2ml	MAST® ASSURE Escherichia Coli POLY D5 (O20, O25, O63, O153, O167)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
6	M12010	2ml	MAST® ASSURE Escherichia Coli POLY D6 (O8, O15, O115, O169)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
7	M12011	2ml	MAST® ASSURE Escherichia Coli POLY D7 (O28ac, O112ac, O124, O136, O144)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
8	M12012	2ml	MAST® ASSURE Escherichia Coli POLY D8 (O29, O143, O152, O164)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
9	M14263	2ml	MAST® ASSURE Escherichia Coli POLY 2 Factors O26, O55, O111, O119, O126	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
10	M14270	2ml	MAST® ASSURE Escherichia Coli POLY 3 Factors O86, O114, O125, O127, O128	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
11	M14287	2ml	MAST® ASSURE Escherichia Coli POLY 4 Factors O44, O112, O124, O142	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.



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11	M12013	2ml	MAST® ASSURE Escherichia coli - Mono factor O1	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
12	M12014	2ml	MAST® ASSURE Escherichia coli - Mono Factor O26	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
13	M12015	2ml	MAST® ASSURE Escherichia coli - Mono factor O86a	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
14	M12016	2ml	MAST® ASSURE Escherichia coli - Mono Factor O111	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
15	M12017	2ml	MAST® ASSURE Escherichia coli - Mono Factor O119	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
16	M12018	2ml	MAST® ASSURE Escherichia coli - Mono Factor O127a	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
17	M12019	2ml	MAST® ASSURE Escherichia coli - Mono factor O128	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
18	M12020	2ml	MAST® ASSURE Escherichia coli - Mono factor O44	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
19	M12021	2ml	MAST® ASSURE Escherichia coli - Mono factor O55	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
20	M12022	2ml	MAST® ASSURE Escherichia coli - Mono factor O125	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
21	M12023	2ml	MAST® ASSURE Escherichia coli - Mono factor O126	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
22	M12024	2ml	MAST® ASSURE Escherichia coli - Mono factor O146	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
23	M12025	2ml	MAST® ASSURE Escherichia coli - Mono factor O166	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
24	M12026	2ml	MAST® ASSURE Escherichia coli - Mono factor O18	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
25	M12027	2ml	MAST® ASSURE Escherichia coli - Mono factor O114	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
26	M12028	2ml	MAST® ASSURE Escherichia coli - Mono factor O142	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
27	M12029	2ml	MAST® ASSURE Escherichia coli - Mono factor O151	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
28	M12030	2ml	MAST® ASSURE Escherichia coli - Mono Factor O157	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
29	M12031	2ml	MAST® ASSURE Escherichia coli - Mono factor O158	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
30	M12032	2ml	MAST® ASSURE Escherichia coli - Mono factor O6	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
31	M12033	2ml	MAST® ASSURE Escherichia coli - Mono factor O27	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
32	M12034	2ml	MAST® ASSURE Escherichia coli - Mono factor O78	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
33	M12035	2ml	MAST® ASSURE Escherichia coli - Mono factor O148	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
34	M12036	2ml	MAST® ASSURE Escherichia coli - Mono factor O159	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
35	M12037	2ml	MAST® ASSURE Escherichia coli - Mono factor O168	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
36	M12038	2ml	MAST® ASSURE Escherichia coli - Mono factor O20	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
37	M12039	2ml	MAST® ASSURE Escherichia coli - Mono factor O25	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
38	M12040	2ml	MAST® ASSURE Escherichia coli - Mono factor O63	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
39	M12041	2ml	MAST® ASSURE Escherichia coli - Mono factor O153	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
40	M12042	2ml	MAST® ASSURE Escherichia coli - Mono factor O167	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
41	M12043	2ml	MAST® ASSURE Escherichia coli - Mono factor O8	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
42	M12044	2ml	MAST® ASSURE Escherichia coli - Mono factor O15	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
43	M12045	2ml	MAST® ASSURE Escherichia coli - Mono factor O115	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
44	M12046	2ml	MAST® ASSURE Escherichia coli - Mono factor O169	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
45	M12047	2ml	MAST® ASSURE Escherichia coli - Mono factor O28ac	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
46	M12048	2ml	MAST® ASSURE Escherichia coli - Mono factor O112ac	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
47	M12049	2ml	MAST® ASSURE Escherichia coli - Mono factor O124	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
48	M12050	2ml	MAST® ASSURE Escherichia coli - Mono factor O136	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
49	M12051	2ml	MAST® ASSURE Escherichia coli - Mono factor O144	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
50	M12052	2ml	MAST® ASSURE Escherichia coli - Mono factor O29	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
51	M12053	2ml	MAST® ASSURE Escherichia coli - Mono factor O143	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
52	M12054	2ml	MAST® ASSURE Escherichia coli - Mono factor O152	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.
53	M12055	2ml	MAST® ASSURE Escherichia coli - Mono factor O164	Liquid stable monovalent antiserum for the determination of specific O antigens for the serological identification of pathogenic Escherichia coli by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
54	M12056	5ml	MAST® ASSURE Escherichia coli - Mono factor H-2	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
55	M12057	5ml	MAST® ASSURE Escherichia coli - Mono factor H-4	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
56	M12058	5ml	MAST® ASSURE Escherichia coli - Mono factor H-5	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
57	M12059	5ml	MAST® ASSURE Escherichia coli - Mono factor H-6	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
58	M12060	5ml	MAST® ASSURE Escherichia coli - Mono factor H-7	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
59	M12061	5ml	MAST® ASSURE Escherichia coli - Mono factor H-9	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
60	M12062	5ml	MAST® ASSURE Escherichia coli - Mono factor H-10	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
61	M12063	5ml	MAST® ASSURE Escherichia coli - Mono factor H-11	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
62	M12064	5ml	MAST® ASSURE Escherichia coli - Mono factor H-12	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
63	M12065	5ml	MAST® ASSURE Escherichia coli - Mono factor H-16	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
64	M12066	5ml	MAST® ASSURE Escherichia coli - Mono factor H-18	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
65	M12067	5ml	MAST® ASSURE Escherichia coli - Mono factor H-19	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
66	M12068	5ml	MAST® ASSURE Escherichia coli - Mono factor H-20	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
67	M12069	5ml	MAST® ASSURE Escherichia coli - Mono factor H-21	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
68	M12070	5ml	MAST® ASSURE Escherichia coli - Mono factor H-27	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
69	M12071	5ml	MAST® ASSURE Escherichia coli - Mono factor H-28	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.



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70	M12072	5ml	MAST® ASSURE Escherichia coli - Mono factor H-34	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
71	M12073	5ml	MAST® ASSURE Escherichia coli - Mono factor H-40	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
72	M12074	5ml	MAST® ASSURE Escherichia coli - Mono factor H-41	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
73	M12075	5ml	MAST® ASSURE Escherichia coli - Mono factor H-42	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
74	M12076	5ml	MAST® ASSURE Escherichia coli - Mono factor H-45	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.
75	M12077	5ml	MAST® ASSURE Escherichia coli - Mono factor H-51	Liquid stable antiserum for the determination of H antigens for the serological identification of pathogenic Escherichia coli by the tube agglutination method.