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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, 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™ Shigella Antisera – for serological identification and epidemiological typing with polyvalent and monovalent (flagellar) antisera typing and grouping Shigella species.	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™ Shigella 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	M10109	2ml	MAST ASSURE Shigella dysenteriae POLY A Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
2	M10110	2ml	MAST ASSURE Shigella dysenteriae POLY A1 Types 8, 9, 10, 11, 12	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
3	M10111	2ml	MAST ASSURE Shigella flexneri POLY B Types I, II, III, IV, V, VI,(Groups(3),4,6&7(8)	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
4	M10112	2ml	MAST ASSURE Shigella boydii POLY C Types 1, 2, 3, 4, 5, 6, 7	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
5	M10113	2ml	MAST ASSURE Shigella boydii POLY C1 Types 8, 9, 10, 11	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
6	M10114	2ml	MAST ASSURE Shigella boydii POLY C2 Types 12, 13, 14, 15	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
7	M10154	2ml	MAST ASSURE Shigella boydii POLY C3 Types 16, 17, 18	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
8	M10115	2ml	MAST ASSURE Shigella sonnei POLY D Phase I & II	Liquid stable polyvalent antiserum for the determination of O antigens for the serological identification of Shigella sonnei by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
9	M10116	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 1	Liquid stable antiserum for the determination of O antigen types for the serological identification of Shigella.
10	M10117	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 2	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
11	M10118	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
12	M10119	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
13	M10120	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
14	M10121	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
15	M10122	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
16	M10123	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
17	M10124	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
18	M10125	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
19	M10152	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.
20	M10153	2ml	MAST ASSURE Shigella dysenteriae - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella dysenteriae by slide agglutination.



Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
21	M10126	2ml	MAST ASSURE Shigella flexneri - Mono Type I	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
22	M10127	2ml	MAST ASSURE Shigella flexneri - Mono Type II	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
23	M10128	2ml	MAST ASSURE Shigella flexneri - Mono Type III	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
24	M10129	2ml	MAST ASSURE Shigella flexneri - Mono Type IV	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
25	M10130	2ml	MAST ASSURE Shigella flexneri - Mono Type V	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
26	M10131	2ml	MAST ASSURE Shigella flexneri - Mono Type VI	Liquid stable antisera for the determination of O antigen types for the serological identification of Shigella.
27	M10132	2ml	MAST ASSURE Shigella flexneri - Mono Group (3)4	Liquid stable antisera for the determination of O antigen group for the serological identification of Shigella.
28	M10133	2ml	MAST ASSURE Shigella flexneri - Mono Group 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.
29	M10134	2ml	MAST ASSURE Shigella flexneri - Mono Group 7 (8)	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella flexneri by slide agglutination.



Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
30	M10135	2ml	MAST ASSURE Shigella boydii - Mono Type 1	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
31	M10136	2ml	MAST ASSURE Shigella Boydii - Mono Type 2	Liquid stable antiserum for the determination of O antigen types for the serological identification of Shigella.
32	M10137	2ml	MAST ASSURE Shigella boydii - Mono Type 3	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
33	M10138	2ml	MAST ASSURE Shigella boydii - Mono Type 4	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
34	M10139	2ml	MAST ASSURE Shigella boydii - Mono Type 5	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
35	M10140	2ml	MAST ASSURE Shigella boydii - Mono Type 6	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
36	M10141	2ml	MAST ASSURE Shigella boydii - Mono Type 7	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
37	M10142	2ml	MAST ASSURE Shigella boydii - Mono Type 8	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
38	M10143	2ml	MAST ASSURE Shigella boydii - Mono Type 9	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
39	M10144	2ml	MAST ASSURE Shigella boydii - Mono Type 10	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
40	M10145	2ml	MAST ASSURE Shigella boydii - Mono Type 11	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
41	M10146	2ml	MAST ASSURE Shigella boydii - Mono Type 12	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
42	M10147	2ml	MAST ASSURE Shigella boydii - Mono Type 13	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
43	M10148	2ml	MAST ASSURE Shigella boydii - Mono Type 14	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
44	M10149	2ml	MAST ASSURE Shigella boydii - Mono Type 15	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
45	M10155	2ml	MAST ASSURE Shigella boydii - Mono Type 16	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.



Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
46	M10156	2ml	MAST ASSURE Shigella boydii - Mono Type 17	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.
47	M10157	2ml	MAST ASSURE Shigella boydii - Mono Type 18	Liquid stable antiserum for the determination of O antigens for the serological identification of Shigella boydii by slide agglutination.

Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
48	M10150	2ml	MAST ASSURE Shigella sonnei - Mono Phase I	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.
49	M10151	2ml	MAST ASSURE Shigella sonnei - Mono Phase II	Liquid stable antisera for the determination of O antigen phases for the serological identification of Shigella.

Serial No.	Device ID Number	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
50	M10104	49x 2ml	MAST ASSURE Shigella Antiserum Set 1 consisting of 8 Polyvalent and 41 Monovalent serum for O antigen typing and grouping.	Liquid stable antisera for the determination of O antigens for the serological identification of Shigella.
51	M10105	19x 2ml	MAST ASSURE Shigella Antiserum Set 2 consisting of 8 Polyvalent and 11 Monovalent serum for O antigen typing and grouping.	Liquid stable antisera for the determination of O antigens for the serological identification of Shigella.
52	M10106	8x 2ml	MAST ASSURE Shigella Antiserum Set 3 consisting of 8 Polyvalent serum O antigen typing and grouping.	Liquid stable antisera for the determination of O antigens for the serological identification of Shigella.