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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 <i>Yersinia enterocolitica</i> Antisera – for serological identification and epidemiological grouping of <i>Yersinia enterocolitica</i> .	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003) GMDN code 30718

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 Yersinia enterocolitica Antisera

Serial No.	Product code	Pack Size	Brand/Trade Name	Indented Purpose of the Medical Device Type
1	M11102	2ml	MAST® ASSURE Yersinia enterocolitica Polyvalent: Group O1, O2 Mixture Antiserum	Liquid stable antisera for the determination of O serogroups of Yersinia enterocolitica by slide agglutination.
2	M11103	2ml	MAST® ASSURE Yersinia enterocolitica Polyvalent: Group O3 Antiserum	Liquid stable antisera for the determination of O serogroups of Yersinia enterocolitica by slide agglutination.
3	M11104	2ml	MAST® ASSURE Yersinia enterocolitica Polyvalent: Group O5 Antiserum	Liquid stable antisera for the determination of O serogroups of Yersinia enterocolitica by slide agglutination.
4	M11105	2ml	MAST® ASSURE Yersinia enterocolitica Polyvalent: Group O9 Antiserum	Liquid stable antisera for the determination of O serogroups of Yersinia enterocolitica by slide agglutination.
5	M11106	2ml	MAST® ASSURE Yersinia enterocolitica Polyvalent: Group O8 Antiserum	Liquid stable antisera for the determination of O serogroups of Yersinia enterocolitica by slide agglutination.