



Mast Group Ltd.
Mast House
Derby Road
Bootle
Merseyside L20 1EA
United Kingdom

Tel. +44 (0) 151 933 7277
Fax +44 (0) 151 944 1332

www.mastgrp.com

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 Vibrio cholerae Antisera – for serological identification and epidemiological typing of <i>Vibrio cholerae</i> .	Self certification Annex III excluding section 6	1501000000 (code registered - 24/03/2003) GMDN code 39537

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 Vibrio cholerae Antisera

Serial No.	Product code	Pack Size	Brand/Trade Name	Intended Purpose of the Medical Device Type
1	M11002	2ml	MAST® ASSURE Vibrio cholerae Polyvalent (O1) Antiserum - POLY (INABA, OGAWA)	Liquid stable antiserum the determination of O antigens for the serological identification of <i>Vibrio cholerae</i> by the slide agglutination method.
2	M11003	2ml	MAST® ASSURE Vibrio cholerae (O1) Monovalent Antiserum - INABA	Liquid stable antiserum the determination of O antigens for the serological identification of <i>Vibrio cholerae</i> by the slide agglutination method.
3	M11004	2ml	MAST® ASSURE Vibrio cholerae (O1) Monovalent Antiserum - OGAWA	Liquid stable antiserum the determination of O antigens for the serological identification of <i>Vibrio cholerae</i> by the slide agglutination method.
4	M15001	2ml	MAST® ASSURE Vibrio cholerae Monovalent Antiserum - O139 (Bengal)	Liquid stable antiserum the determination of O antigens for the serological identification of <i>Vibrio cholerae</i> by the slide agglutination method.