



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](http://www.mastgrp.com)

## EC DECLARATION OF CONFORMITY

We as manufacturer declare in sole, responsibility that the devices described below comply with those provisions which apply to them of the Regulation (EU) 2017/746 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/attached on or after the date hereof, and which bear the CE mark. It is also valid for all IVD medical devices described below/attached 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.

### Intended Purpose:

MAST CRYOBANK® is intended to facilitate the safe and robust cryopreservation of micro-organisms from a variety of sources including, but not limited to; clinical, veterinary, food, and reference culture collections. When used in accordance with instructions it provides a stable cryopreservation environment. MAST CRYOBANK® is intended to be used in conjunction with accessories such as MAST CRYO80/BOX, MAST CRYOBLOCK®, standard microbiological laboratory equipment and consumables. MAST CRYOBANK® amongst other features, enables the repeated stable recovery of stored strains of cryopreserved micro-organisms with known characteristics for quality control and performance testing of *in-vitro* diagnostic tests.

CRYOBLOCK® - For use with CRYOBANK®

**IVDR risk classification:** Class A – Rule 5 (a)

**SRN:** Not yet known

**Basic UDI-DI:** 50561527CryobankKG

**Standards applied:** EN ISO 13485:2016, ISO 9001:2015, EN ISO 14971:2019, 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: 26<sup>th</sup> May 2022

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

Document valid till: 26<sup>th</sup> May 2025



Regulation (EU) 2017/746, Annex VIII  
EC DECLARATION OF CONFORMITY- Self-Certification– General IVD

Annex – list of Mast® CRYOBANK® products

Serial No.	Device ID Number	Product Description	Pack Size	Brand Name
1	CRYO80/M	CRYOBANK® 80 MIXED COLOUR	80 cryovials	MAST® CRYOBANK®
2	CRYO80/B	CRYOBANK® 80 BLUE COLOUR	80 cryovials	MAST® CRYOBANK®
3	CRYO80/G	CRYOBANK® 80 GREEN COLOUR	80 cryovials	MAST® CRYOBANK®
4	CRYO80/Y	CRYOBANK® 80 YELLOW COLOUR	80 cryovials	MAST® CRYOBANK®
5	CRYO80/R	CRYOBANK® 80 RED COLOUR	80 cryovials	MAST® CRYOBANK®
6	CRYO80/BOX	CRYOBANK® BOX	1x box	MAST® CRYOBANK®
7	CRYO/Z	CRYOBLOCK®	1x metal block	MAST® CRYOBANK®
8	CRYO80G/D	CRYOBANK® 80 TROCKEN	1x box	MAST® CRYOBANK®