CORNING

Certificate of Compliance

Corning Incorporated - Life Sciences
1 Becton Circle
Durham NC 27712 USA
www.corning.com/lifesciences
Refer to website for regional contact information.

Product Name	:	Dish 60mm TC IVF 500/case		
Catalog Number	:	353652	**Manufacture Date**	: 2018-02-15
Lot ID	:	8032011		
Expiration Date	:	2022-01-30		

Quality Management System - Complies with the current version of the EN ISO 9001 Standard, the EN ISO 13485 Standard, the Medical Device Directive (MDD) 93/42/EEC as amended with 2007/47/EEC, and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Cytotoxicity - Testing has been conducted to qualify all material resins per USP Class VI, "Requirements for plastic containers and closures", and shown to be non-cytotoxic. Product has been tested and shown to be non-cytotoxic per the requirements of ISO 10993-5, "Biological evaluation of medical devices - Tests for in vitro cytotoxicity".

Non-Pyrogenic - Each lot has been tested and meets the criteria established in the current version of United States Pharmacopeia (USP) Chapter <85>, "Bacterial Endotoxins Test". The acceptance level for product is less than 0.1 EU/mL or 5 EU/device.

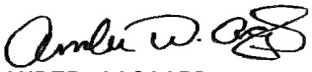
Embryotoxicity - Each lot has been tested for embryotoxicity using the mouse 1-cell embryotoxicity assay. At least 75% of both test and control embryos must reach the hatched and/or expanded blastocyst stage in order for test product to be deemed non-embryotoxic and acceptable for product release.

Tissue Culture - Each lot has been subjected to an actual performance test for growth with a mammalian cell line. Cells are plated to be confluent within 72 hours. A minimum of 90% confluency is required for lot acceptance.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release.

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



AMBER AAGAARD
Quality Manager