CORNING

Certificate of Compliance

Corning Incorporated – Life Sciences
One Becton Circle
Durham, NC 27712
tel: + 1.978.442.2200
www.corning.com/lifesciences
CLSTechServ@Corning.com

Product Name	:	Plate 4 Well TC IVF MEA Tested		
Catalog Number	:	353654	**Manufacture Date**	: 2013/10/08
Batch Number	:	3273972		
Expiration Date	:	2017/09/30		

Quality System Compliance - Falcon® products are manufactured under the most current version of the EN ISO 9001 Standard, the EN ISO 13485 Standard, the Medical Device Directive (MDD) 93/42/EEC, and the FDA Quality System Regulation 21CFR, Section 820.

Sterilization - Product labeled for In Vitro Fertilization is irradiated and dosimetrically released upon US Association for the Advancement of Medical Instrumentation (AAMI) recommended practices in effect at the time of validation. Sterilization records are reviewed and signed off by qualified personnel for product release. Falcon products labeled sterile meet a minimum requirement of 10^{-6} SAL (Sterility Assurance Level).

Tissue Culture Treated - Products labeled tissue culture treated have representative samples subjected to an actual performance test for growth with MRC-5 (human fetal lung fibroblast cells). Cells are plated to be confluent within 72 hours. A minimum of 90% confluency is required for lot acceptance.

Embryotoxicity - Products labeled for In Vitro Fertilization have 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. Non-embryotoxicity records are reviewed and signed off by qualified personnel for product release.

Nonpyrogenic - Products labeled non-pyrogenic have been validated per FDA guidelines on LAL (Limulus Amebocyte Lysate) testing for medical devices and Company guidelines. The acceptance level for product is less than 0.1 EU/ml or 5 EU/device.

Cytotoxicity - Testing is conducted to qualify all material resins using USP and/or ISO 10993 standards for cytotoxicity and have been shown to be non-toxic.

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

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

This product met Corning Incorporated - Life Sciences stringent quality standards at the time of batch/lot release. Any test results reported on this certificate were obtained at the time of release.

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Quality Manager

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