

Certificate of Compliance

Corning Incorporated - Life Sciences 271 County Route 64 Big Flats NY 14814 USA www.corning.com/lifesciences Refer to website for regional contact information.

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Product Name : Plate 96w TC WhtClr w/lid 32cs

Catalog Number : 353377 Manufacture Date : 2015-07-31

Lot ID : E15073D3 **Expiration Date** : 2019-07-31

Quality Management System - Complies with the current version of the ISO 9001 Standard.

Non-Pyrogenic - Validated per FDA guidelines on Pyrogen and Endotoxins testing. The acceptance level for product is ≤ 0.03 EU/ml.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Tissue Culture - Tested for the ability to promote cell attachment and proliferation of mammalian cells. The intra-plate $CV \le 10\%$ for acceptance.

Human DNA Free - Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 5pg.

<code>DNase/RNase Free</code> - Tested by nuclease assay method and found to be free of detectable <code>DNase/RNase</code> contamination. The assay detection limit is $1.3~\rm X10^{-8}$ Kunitz units/ul for <code>DNase</code> and $5.0\rm X10^{-11}$ Kunitz units/ul for <code>RNase</code>.

Sterility - 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^{-3} .

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.

David R Patrick Quality Manager

Creation Date: 2015-09-25 11:16:28