

## **Certificate of Compliance**

Corning Incorporated - Life Sciences 275 River Street Oneonta NY 13820 USA www.corning.com/lifesciences Refer to website for regional contact information.

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Product Name : PLATE, 384W, MICROCAV, BLK CLR

Catalog Number : 4447 Manufacture Date : 2021-10-16

**Lot ID** : 28921001 **Expiration Date** : 2024-10-16

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

**Non-Pyrogenic** - Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is  $\leq 0.10$  EU/ml or  $\leq 4$  EU/device.

Irradiation - This product has been irradiated at a minimum of 10 KGy.

Tissue Culture Treated - Products are treated with a validated standard Plasma TC treatment process.

**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. Key inspections and inline tests are listed below:

Visual Inspection - Pass Packaging Inspection - Pass

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

David P. Kunu DAVID P (DAVE) KIERU Quality Manager

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