

Certificate of Compliance

Corning Incorporated - Life Sciences
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Product Name : 96 Well Fluorescent PCR Storage Rack in Spectrum Pack.
Catalog Number : R-96-PCR-FSP Manufacture Date : 2019-05-16

Lot ID : 13519101 Expiration Date : 2022-05-15

Quality Management System - Complies with the current version of the ISO 9001 Standard and the ISO 13485 Standard.

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 ≤ 0.05 EU/ml or ≤ 2 EU/device.

<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 10^{-5} Kunitz units/ul for <code>DNase</code> and 10^{-9} Kunitz units/ul for <code>RNase</code>.

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 Functional Test - Pass

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

JOSE DOMINGUEZ Quality Manager

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