

Corning Incorporated - Life Sciences
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Product Name	: PLATE, EIA, FLAT, BOTTOM, HIGH, BINDING, STERILE, WITH, LID		
Catalog Number	: 3361	Manufacture Date	: 2020-12-19
Lot ID	: 35420002		
Expiration Date	: 2023-12-19		

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).

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".

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} .

Binding Characteristic - Tested for the attribute of well to well protein binding utilizing a modified ELISA. Binding precision of $\leq 3\%$ CV and high and low wells $\leq 8\%$ from the mean is required for acceptance.

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.



Jason Jens
Plant Quality Manager