

## **Certificate of Compliance**

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

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Product Name : PLT,96WL,STRIPWELL,1X8,HIGH BINDING,CLEAR,FB,NS,WO/LID,BK,25

Catalog Number : 2592 Manufacture Date : 2022-08-08

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).

Animal Content - Product does not contain materials of animal origin.

USP Class VI Testing - Strip 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".

**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.

Olga I Stridum

Olga I Stridiron Monell Plant Quality Manager

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