

## **Certificate of Compliance**

Corning Incorporated - Life Sciences Avenida Industrial del Norte S/N Parque Industrial del Norte Reynosa TAMP 88736 MEX www.corning.com/lifesciences Refer to website for regional contact information.

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**Lot ID** : 27423053

Expiration Date : Unconfirmed Validity

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).

**BSE/TSE** - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

**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".

<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  $10^{-7}$  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.

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

Baudel Ruiz Quality Manager

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