

## **Certificate of Compliance**

Corning Incorporated - Life Sciences 6507 South 400 West Salt Lake City UT 84107 USA www.corning.com/lifesciences Refer to website for regional contact information.

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Product Name : CLUSTER TUBE, 1.2ML, IND, PP, S, 960/CS

Catalog Number : 4411 Manufacture Date : 2021-11-05

Lot ID : 30921000 Expiration Date : 2024-11-05

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

<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>.

**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  $10^{-3}$ .

**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.

Anthony Sloan Quality Manager

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