

## **Certificate of Compliance**

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Product Name : TIPS, CORNING BRAND PIPET, 1000uL INSERT, GRAD, BLUE, NS, H R
Catalog Number : 4715 Manufacture Date : 2015-02-13

**Lot ID** : 04415002

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.

**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". The acceptance level for product is  $\leq$  0.10 EU/ml or  $\leq$  4 EU/device.

**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. 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.

Viviana Nino Garcia Quality Manager

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