CORNING

Certificate of Compliance

Corning Incorporated - Life Sciences
2 Alfred Road
Kennebunk ME 04043 USA
www.corning.com/lifesciences
Refer to website for regional contact information.

Product Name	: PIPETTE,ASPIRATING, 2ML,PS,PLAIN PAPER/PLASTIC WRAP,S,BK,50/		
Catalog Number	: 9016	**Manufacture Date**	: 2019-03-29
Lot ID	: 08819024		
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).

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" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/ml or ≤ 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".

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}.

BSE-TSE - This product is deemed animal free by virtue of not containing materials of animal origin and/or complies with the latest revision of EMA/410/01 section 6.4.

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