

Certificate of Compliance

Product:	Wobble-not [™] Low Insertion Force Serological Pipet
Packaging:	Sample
Catalog Number:	Sample

Lot Number:SampleManufacture Date:MM/DD/YYYYDate of Expiry:MM/DD/YYYY

Pipet material: Virgin polystyrene, meets USP Cytotoxicity ISO 10993-5.2009 relativity test. **Filter material:** Polypropylene fibers, meets USP Cytotoxicity ISO 10993-5.2009 relativity test.

Sterilization: <10⁻⁶ SAL

Pre-sterilization is by gamma radiation with post-sterilization verification. This lot has been processed and tested in accordance with ISO 11137-2. Product samples are bio-burdened.

RNase/DNase: RNase <10⁻⁹ Kunitz units/ μ L, DNase < 10⁻⁷ Kunitz units/ μ L

This product has been tested and is free of any detectable RNase and DNase.

Endotoxin: <0.1 EU/mL

This product has been tested and meets the USP <85> and ANSI/AAMI ST72:2011 guidelines and FDA regulations of endotoxin limit for medical devices at 0.5 EU/mL.

Animal Content:

Resins, inks and packaging materials are not of animal origin and do not contain, make use of, or involve, at any point in the manufacturing process, raw materials of animal origin, including animal proteins.

Volumetric Accuracy: <u>+</u> 2%

This product has been tested and is accurate within $\pm 2\%$ at stated full volume.

CE Mark: Product is verified to CE Directive 93/42/EEC (Medical Devices)

Annex V Production Quality Assurance System

VistaLab Technologies, Inc. is registered ISO 9001:2015

Signed on behalf of the Quality Department:

Jeff Calhoun V.P. Product Development