

Certificate of Compliance

Thomson Instrument Company certifies that this
Product meets the following criteria:

Product

931116-Port-E
Optimum Growth™ 5L Flask w/Port, Sterile, Patented,
4/case

Lot Number:

19160922206501-S2010766

Materials of Construction

The materials used in construction of this product have been tested and met the requirements for the United States Pharmacopoeia (USP) Class VI Biological Test for Plastics, and the requirements of the United States Food and Drug Administration (FDA) for food and beverage contact in 21 CFR 177.

Animal-Origin Free Statement

This product is manufactured from synthetic or manufactured materials and does not contain any raw materials produced from, or substances derived from animal origin and is free from Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE).

LOT CRITERIA

The manufacturing lot was sampled, tested and released by Quality Assurance for the following characteristics:

Critical Dimensions	Pass
Appearance	Pass
Cleanliness	Pass
Packaging Integrity	Pass

Heavy Metals

The resins used in the manufacture of Thomson Instrument Company Disposable flasks do not require reporting under the Superfund Amendment and Reauthorization Act (SARA) Title III, Section 313. They would pass Toxicity Characteristic Leaching Procedure (TCLP) testing.

Sterilization

This lot has been irradiated to achieve a sterility assurance level (SAL) of 10^{-6} . Sterilization of this product has been validated and is routinely audited based on ANSI/AAMI/ISO 11137: Sterilization of health care products – Radiation.

Pyrogens

Representative samples of this product have been tested for endotoxins in accordance with USP <85> Bacterial Endotoxins Test, and have been found to contain less than 0.02 EU/mL.

AUDIT CRITERIA

Audit criteria tests are conducted on a routine basis as appropriate for each configuration manufactured.

Expiration Date

September 2025

Release Date

October 1, 2020

All Thomson Instrument Company labware is for lab use and manufacturing.

Quality Assurance

10-23-2020

Date