



# Certificate of Analysis

Globe Scientific certifies that this product, made from resin material, has been manufactured under controlled conditions and is in compliance with all applicable procedures and specifications.

**Item #:** 6298

**Product Descriptions** Centrifuge tube, 50mL, certified, red screwcap, printed grads, 25/cardboard rack

**Component Material: Tube:** Polypropylene (PP)

**Component Material: Cap:** Polyethylene (PE)

**Standard:** ISO 9001:2015

**Sterilization Method:** Gamma Irradiation (ISO 11137 validated process)

**Sterility Assurance Level (SAL):**  $10^{-6}$

**Globe Scientific certifies that this product has been tested and is completely free of the**

**RNase/DNase:** Products have been tested and are free of any detectable RNase / DNase contamination.

**Nucleic Acids:** Products have been tested and are free from nucleases DNase and RNase.

**Endotoxin (Pyrogen):** The qualification of the endotoxin contamination on implants by LAL analysis based on a kinetic-turbid metric measurement. The method is compliant with USP 161. Result: Kinetic assay  $<0.03$  EU/mL

**Human DNA:** Products have been tested using the Polymerase Chain Reaction (PCR) method and confirm the absence of human DNA contamination.

**Sterility:** The products are irradiated and dosimetrically released based on ISO 11137. Tested and confirmed according to the prescribed standards of USP 35.

**Packaging Sterilization:** Packaging has been validated to maintain sterilization for a minimum of 3 years from manufacture date, as per Stability Study Document No. 8689

**Raw Material:**

Medical grade in accordance with USP Class VI, ISO 10993

Heavy Metals Free

Free of Bisphenol A (BPA), phthalates and cytotoxic effects.

Free of Substances of Very High Concern (SVHC)

REACH compliant

**FDA 21CFR Food Safety:** This product meets the FDA criteria in 21CFR177.1520 for food contact applications listed under conditions of use A through H in 21CFR176.170(c), Table 1.

**Manufacturing Environment:** Fully automated, no touch, production in a cleanroom facility (Class 100,000, ISO Class 8).

**CONEG:** Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

**RoHS:** Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS): Based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).

**Animal Based Raw-Materials (BSE/TSE):** Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMEA/410/01, rev. 3".

**Latex:** No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes.

**Proposition 65:** This product does not contain the substances regulated by California Proposition 65 in concentrations resulting in exposures above the safe harbor levels determined by OEHHA. As such, this product does not require a California Proposition 65 warning label.

**Doug Contreras**  
Director of Operations

02/04/21

Date

