globe® SCIENTIFIC INC. 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 #:	**6271**
Lot #:	**209222**
Expiration Date:	**September 30, 2023**
Product Descriptions	Centrifuge tube, 15mL, PP, PG red A-SC, STR, 50/rack
Component Material: Tube:	Polypropylene (PP),
Component Material: Cap:	High Density Polyethylene (HDPE)
ISO Manufacturing Standard(s):	ISO 9001:2008
Sterilization Method / Range:	Gamma Irradiation (7.7 kGy – 10.5 kGy)
Sterility Assurance Level (SAL):	10^{-3}

Globe Scientific certifies that this product has been tested and is completely free of the following where applicable:

RNase/DNase Free*:
Products were extracted in RNase/DNase free water. The extract was then added to an RNA/DNA standard. The RNA/DNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA/DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.
Result: No visible degradation is present in the product samples. The products can therefore be considered DNase and RNase free.

Non-Cytotoxic*:
Standard: ISO 10993-5: Biological Evaluation of Medical Devices, Part 5: Tests for *In Vitro* Cytotoxicity
Result: The test extract showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was less than a grade 2 (mild reactivity).

Non-Hemolytic*:
Standard: ASTM F756, Standard Practice for Assessment of Hemolytic Properties of Materials. ISO 10993-4, Biological Evaluation of Medical Devices – Part4: Selection of Tests for Interactions with Blood.
Result: The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the CMF-PBS test article extract was 0.0%. The test article in direct contact with blood was non-hemolytic and the test article extract was non-hemolytic.

Non-Pyrogenic*:
Standard: AAMI ST72: Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing (2002/(R)2010). USP 34, National Formulary 29 (USP), General Chapter <85>, Bacterial Endotoxins Test (2011).
Result: Test article extract is < 0.005 EU/mL (total concentration) and < 0.5 EU/device.

Phthalates:
When producing this product, we do not intentionally use any of the 73 substances listed in the "Candidate List of Substances of Very High Concern for Authorization", as of December 19th, 2011.

Latex-Free Statement - The resin manufacturers have supplied a statement that confirms that the materials do not contain Latex. Latex has not been intentionally added in the manufacturing process of this product and it is not used in its packaging.

Statements (other):
We hereby confirm that, to the best of our knowledge, the components of the red die used in the screw cap are not derived from animal sources.

* Testing is completed by a certified independent testing laboratory.

Doug Contreras
Director of Operations

11/05/20
Date

QUALITY globe® SCIENTIFIC INC. ASSURED

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