

Statement on Biocompatibility of TEXIN® Medical Grade Resins



The following uncolored TEXIN® medical grade resins have been evaluated and meet the requirements of certain USP Plastic Class VI and ISO 10993-1 biocompatibility tests:

TEXIN RxT70A 000000	TEXIN RxT50D 000000
TEXIN RxT85A 000000	TEXIN RxT65D 000000
TEXIN RxT90A 000000	TEXIN RxS285 000000

Prior to testing, samples were sterilized by gamma radiation and/or ethylene oxide. Tests conducted include:

Cytotoxicity – MEM Elution	Hemolysis – Rabbit Blood
Sensitization – Kligman Maximization	Genotoxicity – Ames Reverse Mutation
Irritation – Intracutaneous Injection	Intramuscular Implantation
Acute Systemic Injection	USP Physicochemical Tests
Material-Mediated Rabbit Pyrogen Test	Metals Analysis by ICP

For further information regarding TEXIN Medical Grades, contact your Covestro representative or the Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

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Date: 2017-08-25