

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 RxT80A 000000	TEXIN RxT65D 000000
TEXIN RxT85A 000000	TEXIN RxT76D 000000
TEXIN RxT90A 000000	TEXIN RxS285 000000
	TEXIN RxS292 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.

Version 5. The information contained herein is believed to be accurate as of the date of this document. If any of the above mentioned regulations change after the date of declaration, this information is no longer valid.

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Date: 2023-05-01