

Biocompatible KYDEX® sheet has exhibited passing results to both ISO 10993-5: Cytotoxicity and ISO 10993-10: Sensitization and Irritation testing.

Biocompatibility: when material properties make a material or a device compatible with the human body.

KYDEX® Thermoplastics physical properties are rigorously tested to ensure they can be used for specific applications. Chemical resistance, durability (temperature, tensile, and impact strength), and the biocompatibility test results are carefully considered. The results of these tests are deciding factors for choosing the right materials for the right application, and answer questions like: “will the product hold up after cleaning with harsh chemicals and survive the wear and tear of its environment?”

RESOURCES

[KYDEX® Thermoplastic antimicrobial properties resource guide.](#)

[TB 110 G - Biocompatibility of KYDEX® Thermoplastic Sheet](#)

CONTACT appLab™

Lucas Allen, Medical Market Applications Engineer, appLab™

T: +1.570.387.6997 x605

E: allenl@kydex.com

Summary of the ISO methodologies for biocompatibility for skin contact applications:

ISO 10993-5: Cytotoxicity

Cytotoxicity testing determines whether a material contains significant quantities of biologically harmful extractions. Extracts from the test material are exposed to developing cell cultures. The cells are observed for signs of toxicity that include change in size, appearance, or decreased living cells.

ISO 10993-10: Sensitization and Irritation

ISO 10993-10 is a means to minimize the potential exposure of human patients to irritating materials used in medical devices. Extracts from the test material are applied to the test subject via topical and intradermal application. The subject is observed for the development of skin redness, rash, sensitivity, or any abnormal weight gain or loss.

Product	Thickness (Metric)	Textures	Other Details	ISO 10993-5	ISO 10993-10
KYDEX® T	.028" - .400" (.7mm - 10.2mm)	P1, P3, PK	UL 94V-0, 5VA @ 3mm, 5VB @ <3mm	X	X
		P8, PA, PC, PE			
KYDEX® 100	.028" - .400" (.7mm - 10.2mm)	P1, P3	UL 94V-0, 5VA @ 2mm, 5VB < 2mm	X	X
		P8, PC, PE			
KYDEX® 110	.028" - .250" (.7mm - 6.4mm)	P3, PK	Metallic Effect	X	X
		P8, PE			
KYDEX® 430	.028" - .400" (.7mm - 10.2mm)	P1, P3	Meets Ball Pressure 60695-10-2, UL94V-0, 5V @ 1mm	X	X
		P8, PC, PE			
KYDEX® XD	.030" / .040" (.76mm - 1mm)	PK	57"(1448 mm) Standard Width; Lamination Grade	X	X
KYDEX® XD 03	.030" / .040" (.76mm - 1mm)	PK	57"(1448 mm) Standard Width; Lamination Grade	X	X