

INITIAL EVALUATION TESTS FOR CONSIDERATION

BIOCOMPATIBILITY SAFETY TESTING

[Based on ISO 10993-1 AND FDA G95-1 Guidelines]

DEVICE CATEGORIES		BIOLOGICAL EFFECT										
		Initial							Other ⁴			
Body Contact	Contact Duration	Cytotoxicity	Sensitization	Irritation	Systemic Toxicity	Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	
												A – Limited [≤ 24 hrs]
SURFACE DEVICES	Skin	A	●	●	●							
		B	●	●	●							
		C	●	●	●							
	Mucosal Membranes	A	●	●	●							
		B	●	●	●	◇	◇		◇			
		C	●	●	●	◇	●	●	◇		◇	
	Breached or Compromised Surfaces	A	●	●	●	◇						
		B	●	●	●	◇	◇		◇			
		C	●	●	●	◇	●	●	◇		◇	
EXTERNAL COMMUNICATING DEVICES	Blood Path, Indirect ³	A	●	●	●	●				●		
		B	●	●	●	●	◇			●		
		C	●	●	◇	●	●	●	◇	●	●	●
	Tissue ¹ /Bone/ Dentin Communicating	A	●	●	●	◇						
		B	●	●	●	●	●	●	●			
		C	●	●	●	●	●	●	●		●	●
	Circulating Blood ³	A	●	●	●	●		◇ ²		●		
		B	●	●	●	●	●	●	●	●		
		C	●	●	●	●	●	●	●	●	●	●
IMPLANT DEVICES	Tissue / Bone	A	●	●	●	◇						
		B	●	●	●	●	●	●	●			
		C	●	●	●	●	●	●	●		●	●
	Blood ³	A	●	●	●	●	●		●	●		
		B	●	●	●	●	●	●	●	●		
		C	●	●	●	●	●	●	●	●	●	●

¹ "Tissue" includes tissue fluids and subcutaneous spaces.

² For all devices used in extracorporeal circuits.

³ Pyrogenicity / Materials Mediated should be considered.

⁴ Supplemental tests for consideration.

● – ISO Evaluation Tests for Consideration

◇ – Additional tests that the FDA considers may be applicable

For reproductive and biodegradation tests, contact your AppTec Account Manager.