

Biocompatibility Matrix



bioscience
Partner Research Organization

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ISO 10993-1:2009 recommended end points for consideration

Additional FDA recommended end point for consideration

Medical Device Categorization By

Biological Effect

Category	Nature of Body Contact	Contact Duration	Biological Effect											
			Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute / Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	
Surface Device	Intact skin	A	●	●	●									
		B	●	●	●									
		C	●	●	●									
	Mucosal membrane	A	●	●	●									
		B	●	●	●	■	■	■		■				
		C	●	●	●	■	■	●	●	■		■		
	Breached or compromised surface	A	●	●	●	■	■							
		B	●	●	●	■	■	■		■				
		C	●	●	●	■	■	●	●	■		■	■	
External Communicating Device	Blood Path, Indirect	A	●	●	●	●	■				●			
		B	●	●	●	●	■	■			●			
		C	●	●	■	●	■	●	●	■	●	■	■	
	Tissue / Bone / Dentin	A	●	●	●	■	■							
		B	●	●	●	●	■	●	●	●				
		C	●	●	●	●	■	●	●	●		■	■	
	Circulating Blood	A	●	●	●	●	■		■		●			
		B	●	●	●	●	■	●	●	●	●			
		C	●	●	●	●	■	●	●	●	●	■	■	
Implant Device	Tissue / Bone	A	●	●	●	■	■							
		B	●	●	●	●	■	●	●	●				
		C	●	●	●	●	■	●	●	●		■	■	
	Blood	A	●	●	●	●	■		■	●	●			
		B	●	●	●	●	■	●	●	●	●			
		C	●	●	●	●	■	●	●	●	●	■	■	