Nelson Labs®
A Sotera Health company

Biocompatibility Testing Matrix

Tests for Consideration
[Based on ISO 10993-1:2018 and FDA 2016 Guidance on ISO 10993-1]

Device Categories		Contact Duration	Biological Effect												
Body Contact		**A** - Limited (≤24 hours) **B** - Prolonged (>24 hours to ≤30days) **C** - Permanent (>30 days)	Physical/Chemical Information	Cytotoxicity	Sensitization	Irritation	Acute Systemic Toxicity[3]	Material Mediated Pyrogen	Subacute Toxicity[3]	Subchronic Toxicity[3]	Genotoxicity[3]	Implantation	Hemocompatibility	Chronic Toxicity[3]	Carcinogenicity[3]
Surface Devices	Intact Skin	A	X	E	E	E									
		B	X	E	E	E									
		C	X	E	E	E									
	Mucosal Membrane	A	X	E	E	E									
		B	X	E	E	E	E	◊	E			E			
		C	X	E	E	E	E	◊	E	E	E	E		E	
	Breached or Compromised Surface	A	X	E	E	E	E	E							
		B	X	E	E	E	E	E	E	◊		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E
External Communicating Devices	Blood Path, Indirect	A	X	E	E	E	E	E					E		
		B	X	E	E	E	E	E	E	◊			E		
		C	X	E	E	E	E	E	E	E	E	E	E	E	E
	Tissue[1] /Bone/Dentin Communicating	A	X	E	E	E	E	E							
		B	X	E	E	E	E	E	E	◊	E	E			
		C	X	E	E	E	E	E	E	E	E	E		E	E
	Circulating Blood	A	X	E	E	E	E	E			E[2]		E		
		B	X	E	E	E	E	E	E	◊	E	E	E		
		C	X	E	E	E	E	E	E	E	E	E	E	E	E
Implant Devices	Tissue[1]/Bone	A	X	E	E	E	E	E							
		B	X	E	E	E	E	E	E	◊	E	E			
		C	X	E	E	E	E	E	E	E	E	E		E	E
	Blood	A	X	E	E	E	E	E			E	E	E		
		B	X	E	E	E	E	E	E	◊	E	E	E		
		C	X	E	E	E	E	E	E	E	E	E	E	E	E

[1] "Tissue" includes tissue fluids and subcutaneous spaces
[2] For all devices used in extracorporeal circuits
[3] Can be assessed through chemical characterization testing and a toxicological risk assessment.

X - Required
E - ISO Endpoints to be evaluated
◊ - Additional tests which the FDA considers applicable