

医疗器械生物相容性检测要求一览

分类	接触	细胞毒性	致敏	刺激	热原	急性全身毒性	亚急性	亚慢性	慢性	植入	血液相容	遗传毒性	致癌	生殖毒性	降解
表面器械	皮肤	短期	●	●	●										
		长期	●	●	●										
		持久	●	●	●										
	粘膜	短期	●	●	●										
		长期	●	●	●		●	●		●					
		持久	●	●	●		●	●	●	●		●			
	损伤表面	短期	●	●	●	●	●								
		长期	●	●	●	●	●			●					
		持久	●	●	●	●	●	●	●	●		●	●		
外部接入器械	血路	短期	●	●	●	●	●				●				
		长期	●	●	●	●	●				●				
		持久	●	●	●	●	●	●	●	●	●	●	●		
	组织/骨	短期	●	●	●	●	●								
		长期	●	●	●	●	●			●		●			
		持久	●	●	●	●	●	●	●	●		●	●		
	循环血液	短期	●	●	●	●	●				●	●			
		长期	●	●	●	●	●			●	●	●			
		持久	●	●	●	●	●	●	●	●	●	●	●		
植入器械	组织/骨	短期	●	●	●	●	●								
		长期	●	●	●	●	●			●		●			
		持久	●	●	●	●	●	●	●	●		●	●		
	血液	短期	●	●	●	●	●			●	●	●			
		长期	●	●	●	●	●			●	●	●			
		持久	●	●	●	●	●	●	●	●	●	●	●		



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