

Ref	Hazard	Related Part/Component Posing Risk	IR	Solution	RR	Document Reference
C2	<b>ENERGY</b>					
C2.1	Electricity		4		4	Non Electrical
C2.2	Heat		4		4	"
C2.3	Mechanical Force		4		4	"
C2.4	Ionizing Radiation		4		4	"
C2.5	Non Ionizing Radiation		4		4	"
C2.6	Electromagnetic Fields		4		4	"
C2.7	Moving Parts		4		4	
C2.8	Suspended Masses		4		4	
C2.9	Patient Support Failure		4		4	
C2.10	Pressure (Vessel rupture)		4		4	
C2.11	Acoustic pressure		4		4	
C2.12	Vibration		4		4	
C2.13	Magnetic Fields (MRI)		4		4	Non magnetic
C3	<b>BIOLOGICAL</b>					
C3.1	Bio-Burden		4		4	
C3.2	Bio-Contamination		4		4	
C3.3	Bio-Incompatibility		4		4	
C3.4	Incorrect Output (Substance/energy)		4		4	
C3.5	Incorrect Formulation (Chemical Composition)		4		4	
C3.6	Toxicity		4		4	
C3.7	Cross Infection		4	Hospital protocols	4	
C3.8	Pyrogenicity		4		4	

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C3.9	Inability to Maintain Hygienic Standards		4	Hospital protocols	4	
C3.10	Degradation		4		4	
C4.	ENVIRONMENTAL					
C4.1	Electromagnetic Interference		4		4	
C4.2	Inadequate supply of Power or Coolant		4		4	
C4.3	Likelihood of Operation outside Prescribed Environmental Conditions		4		4	
C4.4	Incompatibility with other Devices		4		4	
C4.5	Accidental Mechanical Damage		4		4	
C4.6	Contamination due to Waste Products and or Device Disposal		4		4	
C5	DEVICE USE					
C5.1	Inadequate Labeling		4	Labelling introduced with 2002 version	4	
C5.2	Inadequate Operating Instructions		4		4	
C5.3	Inadequate Specification of Accessories		4		4	
C5.4	Inadequate Specification of Pre-Use Checks		4		4	
C5.5	Over-complicated Operating Instructions		4		4	
C5.6	Unavailable or Separated Operating Instructions		4		4	
C5.7	Use by Unskilled /untrained Personnel		4		4	

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C5.8	Reasonable Foreseeable Abuse		4		4	
C5.9	Insufficient Warning of Side Effects		4		4	
C5.10	Inadequate Warnings of Hazards Likely With Re-use of Single Use Devices		4		4	
C5.11	Incorrect Measurement and other Metrological Aspects		4		4	
C5.12	Incorrect Diagnosis		4		4	
C5.13	Erroneous Data Transfer		4		4	
C5.14	Misrepresentation of Results		4		4	
C5.15	Incompatibility with Consumables /accessories / other Devices		4		4	
C6	FUNCTION FAILURE, MAINTANANCE & AGEING					
C6.1	Inadequacy of Performance Characteristics for the Intended Use		4		4	
C6.2	Lack of, or Inadequate Specification for Maintenance including Post Maintenance Functional Tests		4		4	
C6.3	Inadequate maintenance		4		4	
C6.4	Lack of Adequate Determination of End of Device Life		4	Visual	4	
C6.5	Loss of Mechanical Integrity		4		4	
C6.6	Inadequate Packaging (contamination and/or Deterioration of the Device)		4		4	
C6.7	Improper Use		4		4	

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