

Risk Assessment iaw EN ISO 14971:2000 Annex D : Possible hazards with medical devices.

Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Document referenced.	Sev of Haz.	Like of Haz.	Risk.
D.2	Energy hazards and contributory factors									
D.2.1	Electricity	N/A	1	1	1			1	1	1
D.2.2	Heat	N/A	1	1	1			1	1	1
D.2.3	Mechanical force	Adapter	1	1	1	Recommend not to use force when making connections	User Instructions	1	1	1
D.2.4	Ionising radiation	N/A	1	1	1			1	1	1
D.2.5	Non ionising radiation	N/A	1	1	1			1	1	1
D.2.6	Moving parts	N/A	1	1	1			1	1	1
D.2.7	Unintended motion	N/A	1	1	1			1	1	1
D.2.8	Suspended masses	N/A	1	1	1			1	1	1
D.2.9	Patient support failure	N/A	1	1	1			1	1	1
D.2.10	Pressure (vessel rupture)	N/A	1	1	1			1	1	1
D.2.11	Acoustic pressure	N/A	1	1	1			1	1	1
D.2.12	Vibration	N/A	1	1	1			1	1	1
D.2.13	Magnetic fields (eg. MRI)	N/A	1	1	1			1	1	1
D.3	Biological hazards and contributory factors									
D.3.1	Bio-contamination	Adapter	1	2	2	Easy to Clean	Cleaning Instructions	1	1	1
D.3.2	Bio-incompatibility	Adapter	1	2	2	Plastic Product	Manufacturers Data	1	1	1
D.3.3	Incorrect formulation (chemical composition)	N/A	1	1	1			1	1	1
D.3.4	Toxicity	N/A	1	1	1			1	1	1
D.3.5	Allergenicity	N/A	1	1	1			1	1	1
D.3.6	Mutagenicity	N/A	1	1	1			1	1	1

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D.3.7	Oncogenicity	N/A	1	1	1			1	1	1
D.3.8	Carcinogenicity	N/A	1	1	1			1	1	1
D.3.9	Re and/or cross infection	Adapter	1	1	1	Easy to Clean	Cleaning Instructions	1	1	1
D.3.10	Pyrogenicity	N/A	1	1	1			1	1	1
D.3.11	Inability to maintain hygienic standards	Adapter	2	2	4	Easy to Clean	Cleaning Instructions	2	1	2
D.3.12	Degradation	Adapter	1	1	1	Data Sheets	Life of Material	1	1	1
D.4	Environmental hazards and contributory factors									
D.4.1	Electromagnetic fields	N/A	1	1	1			1	1	1
D.4.2	Susceptibility to electromagnetic interference	N/A	1	1	1			1	1	1
D.4.3	Emissions of electromagnetic interference	N/A	1	1	1			1	1	1
D.4.4	Inadequate supply of power	N/A	1	1	1			1	1	1
D.4.5	Inadequate supply of coolant	N/A	1	1	1			1	1	1
D.4.6	Storage / operation outside prescribed environmental conditions	Adapter	1	2	2	Environmental conditions as per hospital protocols	User Instructions	1	1	1
D.4.7	Incompatibility with other devices with which the product is intended to be used	Adapter	1	2	2	Data Sheets	Product by Size and suitability	1	1	1
D.4.8	Accidental mechanical damage	Adapter	1	1	1	Relatively robust material, if damaged, user to assess damage before use	User Instructions	1	1	1

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D.4.9	Contamination due to waste products and/or device disposal	Adapter	1	1	1	No special disposal required	Risk Report	1	1	1
D.5	Hazards resulting from incorrect output of energy and substances									
D.5.1	Electricity	N/A	1	1	1			1	1	1
D.5.2	Radiation	N/A	1	1	1			1	1	1
D.5.3	Volume	N/A	1	1	1			1	1	1
D.5.4	Pressure	N/A	1	1	1			1	1	1
D.5.5	Supply of medical gases	Adapter	1	2	2	Hospital Protocols	User Instructions	1	1	1
D.5.6	Supply of anaesthetic agents	N/A	1	1	1			1	1	1
D.6	Hazards related to the use of the medical device and contributory factors									
D.6.1	Inadequate labelling	Adapter	1	1	1	No Label required	User Instructions	1	1	1
D.6.2	Inadequate operating instructions	Adapter	1	1	1	Easy to Use	User Instructions	1	1	1
D.6.3	Inadequate specification of accessories	N/A	1	1	1			1	1	1
D.6.4	Inadequate specification of pre-use checks	Adapter	1	1	1	Easy to Use	User Instructions	1	1	1
D.6.5	Over-complicated operating instructions	Adapter	1	1	1	Easy to Use	User Instructions	1	1	1
D.6.6	Inadequate specification of service and maintenance	Adapter	1	1	1	Easy to Use	User Instructions	1	1	1
D.6.7	Use by unskilled / untrained personnel	Adapter	1	2	2	Easy to Use	User Instructions	1	1	1
D.6.8	Reasonable foreseeable misuse	Adapter	1	2	2	Easy to Use	User Instructions	1	1	1
D.6.9	Insufficient warning of side effects	N/A	1	1	1			1	1	1

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D.6.10	Inadequate warnings of hazards likely with re-use of single use devices	Adapter	2	2	4	Product Data Sheets	User Instructions / Cleaning Instructions	2	1	2
D.6.11	Incorrect measurement and other metrological aspects	N/A	1	1	1			1	1	1
D.6.12	Misrepresentation of results	N/A	1	1	1			1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	N/A	1	1	1			1	1	1
D.6.14	Sharp edges or points	Adapter	2	2	4	If damaged, user to assess damage before use	User Instructions	2	1	2
D.7	Inappropriate, inadequate or overcomplicated user interface (man/machine communication)									
D.7.1	Mistakes & judgement errors	N/A	1	1	1			1	1	1
D.7.2	Lapses and cognitive recall errors	N/A	1	1	1			1	1	1
D.7.3	Slips & blunders (mental or physical)	N/A	1	1	1			1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc	N/A	1	1	1			1	1	1
D.7.5	Complex or confusing control system	N/A	1	1	1			1	1	1
D.7.6	Ambiguous or unclear device state	N/A	1	1	1			1	1	1

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D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	N/A	1	1	1			1	1	1
D.7.8	Misrepresentation of results	N/A	1	1	1			1	1	1
D.7.9	Insufficient visibility, audibility or tactility	N/A	1	1	1			1	1	1
D.7.10	Poor mapping of controls to action or of displayed information to actual state	N/A	1	1	1			1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment	N/A	1	1	1			1	1	1
D.8	Hazards arising from function failure, maintenance and ageing and contributory factors									
D.8.1	Erroneous data transfer	N/A	1	1	1			1	1	1
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests	N/A	1	1	1			1	1	1
D.8.4	Inadequate maintenance	N/A	1	1	1			1	1	1
D.8.5	Lack of adequate determination of end of device life	Adapter	1	1	1	User decision based on clarity of plastic & tolerable damage	Risk Analysis Report	1	1	1
D.8.6	Loss of electrical integrity	N/A	1	1	1			1	1	1
D.8.7	Loss of mechanical integrity	Adapter	1	1	1	User decision based on clarity of plastic & tolerable damage	Risk Analysis Report	1	1	1

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D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	N/A	1	1	1			1	1	1
D.8.9	Re-use and/or improper re-use	Adapter	2	2	4	Product Data Sheets	User Instructions	2	1	2
D.8.10	Deterioration in function (gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity) as a result of repeated use	N/A	1	1	1			1	1	1

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