VIAMED

– CE FILE

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 0f Haz.	Risk.
D.2	**Energy hazards and contributory factors**									
D.2.1	Electricity	NA								
D.2.2	Heat	NA								
D.2.3	Mechanical force	NA								
D.2.4	Ionising radiation	NA								
D.2.5	Non ionising radiation	NA								
D.2.6	Moving parts	NA								
D.2.7	Unintended motion	NA								
D.2.8	Suspended masses	NA								
D.2.9	Patient support failure	NA								
D.2.10	Pressure (vessel rupture)	NA								
D.2.11	Acoustic pressure	NA								
D.2.12	Vibration	NA								
D.2.13	Magnetic fields (eg. MRI)	NA								
D.3	**Biological hazards and contributory factors**									
D.3.1	Bio-contamination	1					Z6			
D.3.2	Bio-incompatibility	1					Z6			
D.3.3	Incorrect formulation (chemical composition)	NA					Z6			
D.3.4	Toxicity	NA					Z6			
D.3.5	Allergenicity	NA					Z6			
D.3.6	Mutagenicity	NA								
D.3.7	Oncogenicity	NA								
D.3.8	Carcinogenicity	NA								
D.3.9	Re and/or cross infection	NA								

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.3.10	Pyrogenicity	NA									
D.3.11	Inability to maintain hygienic standards	NA									
D.3.12	Degradation	NA									
D.4	**Environmental hazards and contributory factors**										
D.4.1	Electromagnetic fields	NA									
D.4.2	Susceptibility to electromagnetic interference	NA									
D.4.3	Emissions of electromagnetic interference	NA									
D.4.4	Inadequate supply of power	NA									
D.4.5	Inadequate supply of coolant	NA									
D.4.6	Storage / operation outside prescribed environmental conditions	NA									
D.4.7	Incompatibility with other devices with which the product is intended to be used	NA									
D.4.8	Accidental mechanical damage	NA									
D.4.9	Contamination due to waste products and/or device disposal	NA									
D.5	**Hazards resulting from incorrect output of energy and substances**										
D.5.1	Electricity	NA									
D.5.2	Radiation										
D.5.3	Volume	NA									

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D.5.4	Pressure	NA									
D.5.5	Supply of medical gases	NA									
D.5.6	Supply of anaesthetic agents	NA									
D.6	**Hazards related to the use of the medical device and contributory factors**										
D.6.1	Inadequate labelling	NA									
D.6.2	Inadequate operating instructions	NA?									
D.6.3	Inadequate specification of accessories	N/A									
D.6.4	Inadequate specification of pre-use checks	N/A									
D.6.5	Over-complicated operating instructions	N/A									
D.6.6	Inadequate specification of service and maintenance	N/A									
D.6.7	Use by unskilled / untrained personnel	N/A									
D.6.8	Reasonable foreseeable misuse	N/A									
D.6.9	Insufficient warning of side effects	N/A									
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices	N/A									
D.6.11	Incorrect measurement and other metrological aspects	N/A									
D.6.12	Misrepresentation of results	N/A									
D.6.13	Incompatibility with										

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	consumables / accessories / other devices	N/A								
D.6.14	Sharp edges or points	N/A								
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors	N/A								
D.7.2	Lapses and cognitive recall errors	N/A								
D.7.3	Slips & blunders (mental or physical)	N/A								
D.7.4	Violation or abbreviation of instructions, procedures etc	N/A								
D.7.5	Complex or confusing control system	N/A								
D.7.6	Ambiguous or unclear device state	N/A								
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	N/A								
D.7.8	Misrepresentation of results	N/A								
D.7.9	Insufficient visibility, audibility or tactility	N/A								
D.7.10	Poor mapping of controls to action or of displayed information to actual state	N/A								
D.7.11	Controversial modes or mappings as compared to	N/A								

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	existing equipment										
D.8	**Hazards arising from function failure, maintenance and ageing and contributory factors**										
D.8.1	Erroneous data transfer	N/A									
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests	N/A									
D.8.4	Inadequate maintenance	N/A									
D.8.5	Lack of adequate determination of end of device life	N/A									
D.8.6	Loss of electrical integrity	N/A									
D.8.7	Loss of mechanical integrity	N/A									
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	N/A									
D.8.9	Re-use and/or improper re-use	N/A									
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									

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