Risk Assessment iaw EN ISO 14971:2000 Annex D : Possible hazards with medical devices.Ammended to match EN14971 :2009

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D.2	**Energy hazards and contributory factors**									
D.2.1	Electricity	None	1	1	1	Non required	IEC601/1	1	1	1
	Line voltage	None	1	1	1	Non required	ISO9000:2000	1	1	1
	Leakage enclosure	None	1	1	1	Non required	ISO14971:2009	1	1	1
	Leakage earth	None	1	1	1	Non required	ISO13471:2009	1	1	1
	Patient Leakage	None	1	1	1	Non required	Y1 Design History	1	1	1
	Electric Fields	None	1	1	1	Non required		1	1	1
D.2.2	Heat	None	1	1	1	Non required		1	1	1
	High Temperature	None	1	1	1	Non required	IEC601/1 PtII	1	1	1
	Low Temperature	None	1	1	1	Non required		1	1	1
D.2.3	Mechanical force	None	1	1	1	Non required		1	1	1
	Gravity : Falling	None	1	1	1	Non required		1	1	1
	Suspended masses	None	1	1	1	Non required		1	1	1
	Stored energy	None	1	1	1	Non required		1	1	1
	Torsion,Shear & Tensile	None	1	1	1	Non required		1	1	1
	High Pressure Fluid injection	None	1	1	1	Non required		1	1	1
D.2.4	Ionising radiation	None	1	1	1	Non required	Z12 No Ionisation	1	1	1
D.2.5	Non ionising radiation	None	1	1	1	Non required		1	1	1
D.2.6	Moving parts	None	1	1	1	Non required	D2 Device description	1	1	1
	Moving & positioning patient	None	1	1	1	Non required	D2 Device description	1	1	1
D.2.7	Unintended motion	None	1	1	1	Non required	D2 Device description	1	1	1
D.2.8	Suspended masses	None	1	1	1	Non required	D2 Device description	1	1	1

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D.2.9	Patient support failure	None	1	1	1	Non required	D2 Device description	1	1	1
D.2.10	Pressure (vessel rupture)	None	1	1	1	Non required	D2 Device description	1	1	1
D.2.11	Acoustic pressure	None	1	1	1	Non required	D2 Device description	1	1	1
	Ultrasonic energy	None	1	1	1	Non required		1	1	1
	Infrasound energy	None	1	1	1	Non required	D2 Device descriptionD2	1	1	1
	Sound	None	1	1	1	Non required		1	1	1
D.2.12	Vibration	None	1	1	1	Non required		1	1	1
D.2.13	Magnetic fields (eg. MRI)	None	1	1	1	Non required	D2 Device description	1	1	1
D.3	None									
D.3.1	Bio-contamination	None	2	1	2	Non required	F5 Instructions for use	1	1	1
	Bacteria	None	2	1	2	Non required	F5 Instructions for use	1	1	1
	Viruses	None	1	1	1	Non required		1	1	1
	Other agents (prions)	None	1	1	1	Non required		1	1	1
D.3.2	Bio-incompatibility	None	1	1	1	Non required	Z6 Bio-compatibility	1	1	1
D.3.3	Incorrect formulation (chemical composition)	None	1	1	1	Non required		1	1	1
D.3.4	Toxicity	None	1	1	1	Non required		1	1	1
D.3.5	Allergenicity/ irritancy	None	1	1	1	Non required		1	1	1
D.3.6	Mutagenicity	None	1	1	1	Non required		1	1	1
D.3.7	Oncogenicity	None	1	1	1	Non required		1	1	1
D.3.8	Carcinogenicity	None	1	1	1	Non required	Z11 Carcinogenic substances	1	1	1
D.3.9	Re and/or cross infection	None	2	1	2	Non required	F5 Instructions for use	1	1	1

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D.3.10	Pyrogenicity	None	1	1	1	Non required		1	1	1
D.3.11	Inability to maintain hygienic standards	None	2	1	2	Non required	F5 Instructions for use	1	1	1
D.3.12	Degradation	None	1	1	1	Non required		1	1	1
	Chemical	None	1	1	1	Non required		1	1	1
	Acids or Alkalis	None	1	1	1	Non required		1	1	1
	Contaminates	None	1	1	1	Non required		1	1	1
	Processing aids	None	1	1	1	Non required		1	1	1
	Cleaning, disinfection	None	1	1	1	Non required		1	1	1
	Testing aids	None	1	1	1	Non required		1	1	1
	Medical gases	None	1	1	1	Non required		1	1	1
	Anaesthetic products	None	1	1	1	Non required		1	1	1
D.4	None									
D.4.1	Electromagnetic fields	None	1	1	1	Non required		1	1	1
D.4.2	Susceptibility to electromagnetic interference	None	1	1	1	Non required	D4 EMC	1	1	1
D.4.3	Emissions of electromagnetic interference	None	1	1	1	Non required	D4 EMC	1	1	1
D.4.4	Inadequate supply of power	None	1	1	1	Non required		1	1	1
D.4.5	Inadequate supply of coolant	None	1	1	1	Non required		1	1	1

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D.4.6	Storage / operation outside prescribed environmental conditions	None	1	1	1	Non required		1	1	1
D.4.7	Incompatibility with other devices with which the product is intended to be used	None	1	1	1	Non required		1	1	1
D.4.8	Accidental mechanical damage	None	1	1	1	Non required		1	1	1
D.4.9	Contamination due to waste products and/or device disposal	None	1	1	1	Non required		1	1	1
D.5	None									
D.5.1	Electricity	None	1	1	1	Non required		1	1	1
D.5.2	Radiation	None	1	1	1	Non required		1	1	1
D.5.3	Volume	None	1	1	1	Non required		1	1	1
D.5.4	Pressure	None	1	1	1	Non required		1	1	1
D.5.5	Supply of medical gases	None	1	1	1	Non required		1	1	1
D.5.6	Supply of anaesthetic agents	None	1	1	1	Non required		1	1	1
D.6	**Hazards related to the use of the medical device and contributory factors**									
D.6.1	Inadequate labelling	None	1	1	1	Non required	F7 Labels	1	1	1
D.6.2	Inadequate operating instructions	None	1	1	1	Non required	F5 User Instructions	1	1	1

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Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Document referenced.	Sev of Haz.	Like 0f Haz.	Risk.
	Inadequate description of performance	None	1	1	1	Non required	M3 SpecificationF5 User Instructions	1	1	1
	Inadequate specification of intended use	None	1	1	1	Non required	F5 User Instructions	1	1	1
	Inadequate disclosure of limitations	None	1	1	1	Non required	F5 User Instructions	1	1	1
D.6.3	Inadequate specification of accessories	None	1	1	1	Non required	F5 User Instructions	1	1	1
D.6.4	Inadequate specification of pre-use checks	None	1	1	1	Non required	F5 User Instructions F9 Training	1	1	1
D.6.5	Over-complicated operating instructions	None	1	1	1	Non required	F5 User Instructions	1	1	1
D.6.6	Inadequate specification of service and maintenance	None	1	1	1	Non required		1	1	1
D.6.7	Use by unskilled / untrained personnel	None	1	1	1	Non required	F5 User Instructions F9 Training	1	1	1
D.6.8	Reasonable foreseeable misuse	None	1	1	1	Non required		1	1	1
D.6.9	Insufficient warning of side effects	None	1	1	1	Non required		1	1	1
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices	None	1	1	1	Non required		1	1	1

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D.6.11	Incorrect measurement and other metrological aspects	None	1	1	1	Non required		1	1	1
D.6.12	Misrepresentation of results	None	1	1	1	Non required		1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	None	1	1	1	Non required		1	1	1
D.6.14	Sharp edges or points	None	1	1	1	Non required		1	1	1
D.7	None									
D.7.1	Mistakes & judgement errors	None	1	1	1	Non required		1	1	1
	Incorrect or inappropriate output or functionality	None	1	1	1	Non required		1	1	1
	Erroneous data transfer	None	1	1	1	Non required		1	1	1
	Loss or deterioration in function	None	4	1	4	Non required	F5 Instructions for use F9 Training	1	1	1
D.7.2	Lapses and cognitive recall errors	None	1	1	1	Non required		1	1	1
D.7.3	Slips & blunders (mental or physical)	None	1	1	1	Non required		1	1	1
	Rule based failure	None	1	1	1	Non required		1	1	1

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	Knowledge based failure	None	1	1	1	Non required		1	1	1
	Routine violation	None	1	1	1	Non required		1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc	None	1	1	1	Non required		1	1	1
D.7.5	Complex or confusing control system	None	1	1	1	Non required		1	1	1
D.7.6	Ambiguous or unclear device state	None	1	1	1	Non required		1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	None	1	1	1	Non required		1	1	1
D.7.8	Misrepresentation of results	None	1	1	1	Non required		1	1	1
D.7.9	Insufficient visibility, audibility or tactility	None	1	1	1	Non required		1	1	1
D.7.10	Poor mapping of controls to action or of displayed information to actual state	None	1	1	1	Non required		1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment	None	1	1	1	Non required		1	1	1
D.8	None									

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D.8.1	Erroneous data transfer	None	1	1	1	Non required		1	1	1
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests	None	1	1	1	Non required		1	1	1
D.8.4	Inadequate maintenance	None	1	1	1	Non required		1	1	1
D.8.5	Lack of adequate determination of end of device life	None	4	1	4	Non required	F5 User Instructions F9 Training	1	1	1
D.8.6	Loss of electrical integrity	None	1	1	1	Non required		1	1	1
D.8.7	Loss of mechanical integrity	None	1	1	1	Non required		1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	None	1	1	1	Non required		1	1	1
D.8.9	Re-use and/or improper re-use	None	1	1	1	Non required		1	1	1
D.8.10	Deterioration in function (gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity)	None	1	1	1	Non required		1	1	1

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	as a result of repeated use									

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