

**Risk assessment iaw EN ISO 14971:2000 Annex A : Identification of medical device characteristics that could impact on safety.**

Section	Question	Answer Y / N	Risk Y / N
A.2.1	Q. What is the intended use?		
	Diagnosis?	Y	Y
	Prevention?	N	N
	Monitoring?	N	N
	Treatment or alleviation of disease?	N	N
	Compensation for injury or handicap?	N	N
	Replacement or modification of anatomy?	N	N
	Control of conception?	N	N
	Q. What is the intended purpose?		
	Life sustaining?	N	N
	Life supporting?	N	N
	O. How is the medical device to be used?		
	The patient can control the use?	N	N
	The patient can influence the use?	N	N
	Mental abilities of the user ?	N	N
	Physical abilities of the user?	N	N
	Skill of the user?	N	N
	Training of the user?	N	N
	Used by handicapped persons?	N	N
	Used by the elderly?	N	N
	Used by children?	N	N
	Used by individuals with various skill levels?	Y	Y
	Used by individuals from various cultural backgrounds?	Y	N

	The period of contact? A. Transient	Y	N
	The frequency of contact? A. During required use.	Y	N
	Invasive contact?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
	Implantation?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
	Q. What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the		
	Single substance?	N/A	N/A
	Range of substances?		
	The maximum and minimum transfer rates and control thereof? A.		
	O. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls		
	The shelf life?	N/A	N/A
	Any limitation on the number of re-use cycles?		
	Any limitation type of sterilization process to be used?		
	Limitation on the number of cleaning cycles?		
	The effectiveness of routine cleaning and disinfection?		
	Temperature?	N/A	N/A
	Humidity?		
	Atmospheric gas composition?		
	Pressure and light?		
	Light?		
	The variables measured?	N/A	N/A
	The accuracy?		
	The precision of the measurement results?		

A 2 11	Q Is the medical device interpretative?	N	N
	Conclusions are presented by the medical device from input data?	N/A	N/A
	Conclusions are presented by the medical device from acquired data?		
	Conclusions are presented by the medical device from the algorithms used?		
	Conclusions are presented by the medical device from input or acquired data, the algorithms used and confidence limits?		
A 2 12	Q To what level does the medical device comply for each of the following? (4 = Intolerable, 3 = Critical, 2 = Tolerable, 1 = Insignificant)	N	N
A 2 13	Q Are there any other hazards to be considered?	N	N
	Noise?	N/A	N/A
	Vibration?		
	Heat?		
	Radiation?		
	Ionizing?		
	Non-ionizing?		
	Ultraviolet?		
	Visible?		
	Infrared?		
	Contact temperatures?		
	Leakage currents?		
	Electric fields?		
	Magnetic fields?		
	Discharge of chemicals?		
	Discharge of waste products?		
	Discharge of body fluids?		
	Operational?	N/A	N/A
	Transport storage environments?		
	Light?		
	Temperature?		
	Vibrations?		
	Spillage?		
	Susceptibility to variations in power?		
	Susceptibility of cooling supplies?		
	Electromagnetic interference?		

A 2 15	Does the medical device influence the environment?	N	N
	The effects on power supplies?	N/A	N/A
	The effects cooling supplies?		
	Emission of toxic materials?		
	The generation of electromagnetic interference?		
A 2 16	Are there essential components associated with the medical device?	N	N
A 2 17	Is the device intended to be used in a clinical setting?	N	N
	Carried out by the operator?	N/A	N/A
	Carried out by the user?		
	Carried out by a specialist? (Manufacturer)		
	Are special substances necessary for proper maintenance and/or calibration?		
	Is special equipment necessary for proper maintenance and/or calibration?		
	Is software intended to be installed?	N	N
	Is software intended to be verified?	N	N
	Is software intended to be modified?	N	N
	Labeling?	N/A	N/A
	Indicators?		
	The disposal of such medical devices?		
	Ergonomic?	N/A	N/A
	Cumulative effects?		
	Under the control of the user?	Y	N
	Controlled by interaction with other persons?	N	N
	Ageing?	Y	N
	Battery depletion?	N	N
	User care?	Y	N
	Does it contain toxic material?	N/A	N/A

	Does it contain hazardous material?		
	Does it contain recyclable material?		
A 2.25	Does installation or use of the medical device require special training?	N	N
A 2.26	Will new manufacturing processes need to be established or introduced?	N	N
A 2.27	Is successful application of the medical device critically dependent on human factors such as the user interface?	N	N
A 2.27.1	Does the medical device have connection points or components?	Y	N
	Connections?	Y	N
	Connection force?	N	N
	Feedback on connection integrity?	N	N
	Over tightening?	N	N
	Under tightening?	N	N
	Spacing?	N	N
	Coding?	N	N
	Grouping?	N	N
	Mapping,	N/A	N/A
	Modes of feedback?		
	Blunders?		
	Slips?		
	Control differentiation?		
	Visibility?		
	Direction of activation or change?		
	Are the controls continuous?		
	Are the controls discrete?		
	The reversibility of settings or actions?		
	Visibility in various environments?	N/A	N/A
	Orientation?		
	Populations and perspectives?		
	The clarity of the presented information?		
	Units?		
	Colour coding?		
	The accessibility of critical information?		

A 227.4	Q Is the medical device controlled by a menu?	NI	NI
	Complexity?	N/A	N/A
	Number of layers?		
	Awareness of state		
	Location of settings?		
	Navigation method?		
	Number of steps per action?		
	Sequence?		
	Clarity and memorization problems?		
	Importance of control function relative to its accessibility?		
	Grips?	N/A	N/A
	Handles?		
	Wheels?		
	Brakes?		
	Mechanical stability?		
	Mechanical durability?		