

## Appendix 5 – Identification of Hazards and Characteristics Related to Safety (according to ISO/TR 24971:2020)

Safety characteristics ID:	
Medical device name:	
Basic UDI:	
EMDN CODE:	
Risk Management Plan ID:	
Date:	

**Commented [AES1]:** Include a unique code for this document

**Commented [AES2]:** You can find the right EMDN CODE for

**Commented [AES3]:** Include the date when this document is completed.

ISO/TR 24971:2020 clause	Question	Answer/Comments
A.2.1	What is the intended use, and how is the medical device to be used?	
A.2.2	Is the medical device intended to be implanted?	
A.2.3	Is the medical device intended to come into contact with the patient or other persons?	
A.2.4	What materials and/or components are utilized in the medical device or are used with, or are in contact with, the medical device?	
A.2.5	Is the medical device intended to be used in the water?	
A.2.6	Is the medical device intended to be used in the air?	
A.2.7	Is the medical device intended to be used in the presence of electromagnetic fields, radiofrequency fields, or electromagnetic interference?	
A.2.8	Is the medical device intended to be used in the presence of other medical devices or equipment?	

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A.2.9	Is the medical device intended to be routinely cleaned and disinfected by the user?	
A.2.10	Does the medical device modify the patient environment?	
A.2.11	Are measurements taken?	
A.2.12	Is the medical device interpretative?	
A.2.13	Is the medical device intended for use in conjunction with other medical devices, medicines, or other medical technologies?	
A.2.14	Are there unwanted outputs of energy or substances?	
A.2.15	Is the medical device susceptible to environmental influences?	
A.2.16	Does the medical device influence the environment?	
A.2.17	Does the medical device require maintenance or adjustment?	
A.2.18	Is maintenance or adjustment required?	
A.2.19	Does the medical device require software?	
A.2.20	Does the medical device utilize software?	
A.2.21	Does the medical device store data?	
A.2.22	Does the medical device store data other than patient data?	
A.2.23	Does the medical device have a network port?	
A.2.24	Are there any Bluetooth or infrared capabilities?	
A.2.25	Is user interaction with the medical device required?	
A.2.26	What determines the status of the medical device?	
A.2.27	Is the medical device intended for single use?	
A.2.28	Is safe decommissioning or disposal of the medical device required?	

A.2.28	Does installation or use of the medical device require special training or special skills?	
A.2.29	How will information for safety be provided?	
A.2.30	Are new manufacturing processes established or introduced?	
A.2.31	Is successful application of the medical device dependent on the usability of the user interface?	
A.2.31.1	Can the user interface design features contribute to use error?	
A.2.31.2	Is the medical device used in an environment where distractions can cause use error?	
A.2.31.3	Does the medical device have connecting parts or accessories?	
A.2.31.4	Does the medical device have a control interface?	
A.2.31.5	Does the medical device display information?	
A.2.31.6	Is the medical device controlled by a user?	
A.2.31.7	Is the successful use of the medical device dependent on a user's knowledge, skills, and abilities?	
A.2.31.8	Will the medical device be used by persons with specific needs?	
A.2.31.9	Can the user interface be used by people with disabilities?	
A.2.32	Does the medical device include an alarm system?	
A.2.33	In what ways might the medical device be involved in hazardous events?	
A.2.34	Is the medical device intended to be mobile or portable?	
A.2.35	Does the use of the medical device depend on operator performance?	
A.2.36	Does the medical device have a degree of complexity?	

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A.2.37	Does the medical device produce an output that is used as an input in determining clinical action?	
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