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?	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	

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?	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	

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?	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	
[illegible]	[illegible]	

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