Company Name – Project Name

**Preliminary Hazards List**Document Number

Rev 0 DRAFT

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**Revision History**

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# Purpose

The purpose of this document is to identify the Preliminary Hazards (e.g., potential hazards and hazardous situations) that might occur with the use of Company Name’s Product Name device. Identification of potential hazards and hazardous situations early in the design process can expose high-risk items that may be avoided by design.

# References

## Applicable Regulations and Standards

1. ISO 14971:2019 Medical devices – Application of risk management to medical devices
2. ISO/TR 24971:2020 Medical devices – Guidance on the application of ISO 14971
3. Text

## Process Documents

1. [doc #] *Project Name* Risk Management Plan
2. [doc #] *Project Name* Hazard-Harm-Severity Table
3. [doc #] *Project Name* Product Risk Analysis Worksheet
4. [doc #] *Project Name* Use Specification

## Project Documents

1. [doc #] Project Name Project Development Plan
2. [doc #] *Project Name* User Requirements Specification
3. 3rd reference

# Inputs

The following inputs were reviewed for identification of the applicable hazards and hazardous situations:

* Intended Use - see S1-ENG-PROD-UXD-00XX, Project Name Use Specification
* Characteristics Related to Safety – See APPENDIX A
* Applicable Regulations and Safety Standards – listed in section 2.1 above
* ISO 14971:2019 Annex C.2 Examples of Hazards
* Post-production Data – see Attachment A

# Characteristics Related to Safety

Questions on characteristics related to safety from ISO/TR 24971:2020 Annex A have been reviewed, and responses for applicability to Company Name’s Project Name Infusion Pump and Administration Set are documented in table below. Applicability of the questions to the system is noted by checking the appropriate box “yes” or “no”, with comments provided for further clarification.

| **Characteristics Related to Safety** | | | | |
| --- | --- | --- | --- | --- |
| **Ref. #** | **Question** | **Yes** | **No** | **Comments** |
| **A.2.1** | **What is the intended use and how is the medical device to be used?**  Factors that should be considered include:  — what is the medical device’s role relative to:  — diagnosis, prevention, monitoring, treatment or alleviation of disease,  — diagnosis, monitoring, treatment or alleviation of or compensation for an injury,  — investigation, replacement, modification or support of anatomy or a physiological process, or  — control of conception?  — what are the indications for use (e.g., patient population, user profile, use environment)?  — what are the contra-indications?  — does the medical device sustain or support life?  — is special intervention necessary in the case of failure of the medical device?  — can the performance of the medical device be impacted in the event of a security breach (performance degradation or loss of availability)?  — can unauthorized access, unauthorized activities, or loss of data affect the medical device safety? |  |  |  |
| **A.2.2** | **Is the medical deviceintended to be implanted?**  Factors that should be considered include the location of implantation, the characteristics of the patient population, age, weight, physical activity, the effect of ageing on implant performance, the expected lifetime of the implant, the reversibility of the implantation, whether the implant can be modified or configured while implanted and the access connection to perform this modification or configuration (e.g., physical access point or wireless connection to the implanted medical device). |  |  |  |
| **A2.3** | **Is the medical device intended to be in contact with the patient or other persons?**  Factors that should be considered include the nature of the intended contact, i.e., surface contact, invasive contact, or implantation and, for each, the period and frequency of contact. |  |  |  |
| **A2.4** | **What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?**  Factors that should be considered include:  — compatibility with relevant substances,  — compatibility with tissues or body fluids,  — whether characteristics relevant to safety are known,  — is the medical device manufactured utilizing materials of animal origin? |  |  |  |
| **A2.5** | **Is energy delivered to or extracted from the patient?**  Factors that should be considered include:  — the type of energy transferred,  — its control, quality, quantity, intensity and duration,  — whether energy levels are higher than those currently used for similar medical devices. |  |  |  |
| **A2.6** | **Are substances delivered to or extracted from the patient?**  Factors that should be considered include:  — whether the substance is delivered or extracted,  — whether it is a single substance or range of substances,  — the maximum and minimum transfer rates and control thereof. |  |  |  |
| **A2.7** | **Are biological materials processed by the medical device for subsequent reuse, transfusion or transplantation?**  Factors that should be considered include the type of process and substance(s) processed (e.g., auto-transfusion, dialysis, blood component or cell therapy processing). |  |  |  |
| **A2.8** | **Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?**  Factors that should be considered include:  — whether the medical device is intended for single use or reuse packaging,  — shelf-life issues,  — limitation on the number of reuse cycles,  — method of product sterilization,  — the impact of other sterilization methods not intended by the manufacturer. |  |  |  |
| **A2.9** | **Is the medical device intended to be routinely cleaned and disinfected by the user?**  Factors that should be considered include the types of cleaning or disinfecting agents to be used and any limitations on the number of cleaning cycles. The design of the medical device can influence the effectiveness of routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the medical device. |  |  |  |
| **A2.10** | **Does the medical device modify the patient environment?**  Factors that should be considered include:  — temperature,  — humidity,  — atmospheric gas composition,  —pressure,  — light. |  |  |  |
| **A2.11** | **Are measurements taken?**  Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results, as well as whether the measurement apparatus or data can be compromised. In addition, the need for calibration and maintenance should be considered |  |  |  |
| **A2.12** | **Is the medical device interpretative?**  Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms used, and confidence limits. Special attention should be given to unintended applications of the data or algorithm, as well as unauthorized manipulation or changes to algorithms and data. |  |  |  |
| **A2.13** | **Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?**  Factors that should be considered include:  — identifying any other medical devices, medicines or other medical technologies that can be involved,  — the potential problems associated with interactions (such as the medical device impacting the performance of other medical devices), and  — whether the patient follows the instructions for the therapy. |  |  |  |
| **A2.14** | **Are there unwanted outputs of energy or substances?**  Energy-related factors that should be considered include noise and vibration, heat, radiation (including ionizing, non-ionizing, and ultraviolet/visible/infrared radiation), contact temperatures, leakage currents, and electric or magnetic fields.  Substance-related factors that should be considered include substances used in manufacturing, cleaning or testing having unwanted physiological effects if they remain in the product. Other substance-related factors that should be considered include discharge of chemicals, waste products, and body fluids. |  |  |  |
| **A2.15** | **Is the medical device susceptible to environmental influences?**  Factors that should be considered include the operational, transport and storage environments. These include light, temperature, humidity, vibrations, spillage, susceptibility to variations in power and cooling supplies, and electromagnetic interference. |  |  |  |
| **A2.16** | **Does the medical device influence the environment?**  Factors that should be considered include:  — the effects on power and cooling supplies,  — emission of toxic materials,  — the generation of electromagnetic disturbance. |  |  |  |
| **A2.17** | **Does the medical device require consumables or accessories?**  Factors that should be considered include specifications for such consumables or accessories and any restrictions placed upon users in their selection of these. |  |  |  |
| **A2.18** | **Is maintenance or calibration necessary?**  Factors that should be considered include:  — whether maintenance or calibration are to be carried out by the user or by a specialist,  — whether special substances or equipment are needed for proper maintenance or calibration,  — traceability of the calibrator values to a higher order reference,  — how to determine when maintenance or recalibration is needed,  — how to verify that calibration is (still) acceptable. |  |  |  |
| **A2.19** | **Does the medical device contain software?**  Factors that should be considered include whether software is intended to be installed, verified, modified or exchanged by the user or by a specialist, and the authenticity of a software update. |  |  |  |
| **A2.20** | **Does the medical device allow access to information?**  Factors that should be considered include accessible Ethernet ports, USB ports, serial ports, and removable hard drives. |  |  |  |
| **A2.21** | **Does the medical device store data critical to patient care?**  Factors that should be considered include the possibility of the data being modified or corrupted, unauthorized access to the data, and the consequences for the patients. |  |  |  |
| **A2.22** | **Does the medical device have a restricted shelf life?**  Factors that should be considered include whether the medical device can deteriorate over time, the impact of storage conditions and primary packaging, the communication of the expiry date (by labelling or an indicator), possibility of use after the expiry date, and the disposal of expired medical devices. |  |  |  |
| **A2.23** | **Are there any delayed or long-term use effects?**  Factors that should be considered include ergonomic and cumulative effects. Examples could include pumps for saline that corrode over time, mechanical fatigue, loosening of straps and attachments, vibration effects, labels that wear or fall off, long-term material degradation. |  |  |  |
| **A2.24** | **To what mechanical forces will the medical device be subjected?**  Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user or controlled by interaction with other persons |  |  |  |
| **A2.25** | **What determines the lifetime of the medical device?**  Factors that should be considered include battery depletion, deterioration of materials and failure of components due to ageing, wear, fatigue or repeated use. The availability of spare parts should be considered as well. |  |  |  |
| **A2.26** | **Is the medical device intended for single use?**  Factors that should be considered include:  — whether the medical device self-destructs after use,  — whether it is obvious to the user that the medical device has been used. |  |  |  |
| **A2.27** | **Is safe decommissioning or disposal of the medical device necessary?**  Factors that should be considered include the waste products that are generated during the disposal of the medical device itself, and the proper sanitization (removal) of all sensitive data on the medical device. For example, does it contain hazardous material (e.g., toxic chemical or biological agent), or is the material recyclable? If the medical device stores data, proper handling and security of the stored data should be considered, including data removal and retention |  |  |  |
| **A2.28** | **Does installation or use of the medical device require special training or special skills?**  Factors that should be considered include the complexity and novelty of the medical device and the knowledge, skills and ability of the persons installing, maintaining or using the medical device. This can include training, education, competence assessment, certification or qualification. |  |  |  |
| **A2.29** | **How will information for safety be provided?**  Factors that should be considered include:  — whether information will be provided directly to the end user by the manufacturer or will it involve the participation of third parties such as installers, care providers, health care professionals, laboratory directors or pharmacists and whether this will have implications for training,  — commissioning and transferring to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills,  — based on the type and expected lifetime of the medical device, whether re-training or re-certification of users or service personnel would be indicated. |  |  |  |
| **A2.30** | **Are new manufacturing processes established or introduced?**  Factors that should be considered include the application of new or innovative technology and changes in the scale of production. This can also involve changes in contract manufacturing, suppliers and vendors. |  |  |  |
| **A2.31** | **Is successful application of the medical device dependent on the usability of the user interface?** |  |  |  |
| **A2.31.1** | **Can the user interface design features contribute to use error?**  Factors that should be considered include controls and indicators, symbols used, ergonomic features, physical design and layout, hierarchy of operation, menus for software-driven medical devices, visibility of warnings, audibility of alarms, standardization of color coding. |  |  |  |
| **A2.31.2** | **Is the medical device used in an environment where distractions can cause use error?**  Factors that should be considered include:  — the consequence of use error,  — whether the distractions are commonplace,  — whether the user can be disturbed by an infrequent distraction,  — whether repetitive stress can reduce the user’s awareness or attention. |  |  |  |
| **A2.31.3** | **Does the medical device have connecting parts or accessories?**  Factors that should be considered include the possibility of wrong connections, similarity to other products’ connections, connection force, feedback on connection integrity, and over- and under-tightening. |  |  |  |
| **A2.31.4** | **Does the medical device have a control interface?**  Factors that should be considered include spacing, coding, grouping, mapping, modes of feedback, blunders, slips, control differentiation, visibility, direction of activation or change, whether the controls are continuous or discrete, and the reversibility of settings or actions. |  |  |  |
| **A2.31.5** | **Does the medical device display information?**  Factors that should be considered include visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information |  |  |  |
| **A2.31.6** | **Is the medical device controlled by a menu?**  Factors that should be considered include complexity and number of layers, awareness of state, location of settings, navigation method, number of steps per action, sequence clarity and memorization problems, and importance of control function relative to its accessibility and the impact of deviating from specified operating procedures. |  |  |  |
| **A2.31.7** | **Is the successful use of the medical device dependent on a user’s knowledge, skills and abilities?**  Factors that should be considered include:  — the (intended) users, their mental and physical abilities, skill and training,  — the use environment, ergonomic aspects, installation requirements,  — the capability of intended users to control or influence the use of the medical device; and  — the personal characteristics of intended users that can affect their ability to successfully interact with the medical device. |  |  |  |
| **A2.31.8** | **Will the medical device be used by persons with specific needs?**  Factors that should be considered include:  — users with special characteristics, such as disabled persons, the elderly and children, who might need assistance by another person to enable the use of a medical device,  — users having wide-ranging skill levels and differing cultural backgrounds and expectations that could lead to differences in what is considered appropriate application of the medical device. |  |  |  |
| **A2.31.9** | **Can the user interface be used to initiate unauthorized actions?**  Factors that should be considered include whether the user interface allows the user to enter an operation mode with restricted access (e.g., for maintenance or special use), which increases the possibility of use error and thereby the associated risks, and whether the user becomes aware of having entered such operation mode. |  |  |  |
| **A2.32** | **Does the medical device include an alarm system?**  Factors that should be considered are the risk of false alarms, missing alarms, disconnected alarm systems, unreliable remote alarm systems, and the user’s ability of understanding how the alarm system works. |  |  |  |
| **A2.33** | **In what ways might the medical device be misused (deliberately or not)?**  Factors that should be considered are incorrect use of connectors, disabling safety features or alarms, neglect of manufacturer’s recommended maintenance, unauthorized access to the medical device or to medical device functions. |  |  |  |
| **A2.34** | **Is the medical device intended to be mobile or portable?**  Factors that should be considered are the need for grips, handles, wheels or brakes, and the need for mechanical stability and durability. |  |  |  |
| **A2.35** | **Does the use of the medical device depend on essential performance?**  Factors that should be considered are, for example, the characteristics of the output of life supporting medical devices or the operation of an alarm. See IEC 60601-1 for a discussion of essential performance of medical electrical equipment and medical electrical systems. |  |  |  |
| **A2.36** | **Does the medical device have a degree of autonomy?**  Factors that should be considered include:  — awareness of the user when the medical device with a degree of autonomy generates an error, alarm or failure,  — awareness of the user when intervention in an autonomously performed action is required,  — the ability of the user to intervene in or to abort an action that is performed autonomously; and  — the ability of the user to select and perform proper corrective actions. |  |  |  |
| **A2.37** | **Does the medical device produce an output that is used as an input in determining clinical action?**  Factors that should be considered include whether incorrect or delayed outputs can result in direct or indirect risks to patients, e.g., an incorrect diagnosis resulting in delayed or omitted therapy for a patient. |  |  |  |

# Preliminary Hazards List

A review of all sources of information listed in this document has been completed and all relevant information has been used to document the Preliminary Hazards List below for Company Name’s Product Name device.

| **Input Source Data Reference(s)** | **Hazard Category** | **Hazard** | **Hazardous Situation** |
| --- | --- | --- | --- |
|  | Acoustic Energy | Infrasound |  |
|  |  | Sound Pressure |  |
|  |  | Ultrasonic |  |
|  | Electric Energy | Electric Fields |  |
|  |  | Leakage Current |  |
|  |  | Magnetic Fields |  |
|  |  | Static Discharge |  |
|  |  | Voltage |  |
|  | Mechanical Energy | Falling Objects |  |
|  |  | High Pressure |  |
|  |  | Moving Parts |  |
|  |  | Vibration |  |
|  |  | Vacuum Pressure |  |
|  |  | Sharp Edges |  |
|  | Potential (stored) energy | Bending |  |
|  |  | Compression |  |
|  |  | Cutting, Shearing |  |
|  |  | Gravitational pull |  |
|  |  | Suspended Mass |  |
|  |  | Tension |  |
|  |  | Torsion |  |
|  | Radiation Energy | Ionizing Radiation |  |
|  |  | Non-Ionizing Radiation |  |
|  | Thermal Energy | High Temperature |  |
|  |  | Low Temperature |  |
|  | Biological Energy | Microbial Contamination (Bacteria, Virus, Fungi, Toxins, parasites, etc.) |  |
|  | Chemical Agents | Carcinogenic, mutagenic, reproductive |  |
|  |  | Caustic, Corrosive (acidic, alkaline, oxidants, etc.) |  |
|  |  | Flammable, combustible, explosive |  |
|  |  | Fumes, Vapors |  |
|  |  | Particles (including micro-and nano-particles) |  |
|  |  | Pyrogenic |  |
|  |  | Solvents |  |
|  |  | Toxic Substances (asbestos, heavy metals, inorganic toxicants, organic toxicants, silica, etc.) |  |
|  | Immunological Agents | Allergenic (antiseptic substances, latex, etc.) |  |
|  |  | Immunosuppressive |  |
|  |  | Chemical Irritants (residues from cleaning, manufacturing, or processing) |  |
|  |  | Sensitizing agents |  |
|  | Data | Loss of Data Access |  |
|  |  | Loss of Data Availability |  |
|  |  | Loss of Data Confidentiality |  |
|  |  | Incomplete Data Transfer |  |
|  |  | Loss of Data Integrity |  |
|  | Delivery | Incorrect quantity delivered |  |
|  |  | Incorrect rate of delivery |  |
|  | Diagnostic | Incorrect Examination Result |  |
|  |  | Delayed Examination Result |  |
|  |  | Incorrect Information Accompanying Result |  |
|  |  | Image Artifacts |  |
|  |  | Incorrect Image Resolution |  |
|  |  | Incorrect Patient Identity / Information |  |
|  | Functionality | Incorrect or Missing Alert, Notification, or Alarm |  |
|  |  | Loss of Function |  |
|  |  | Critical Performance |  |
|  |  | Measurement |  |