Product Name: EXAMPLE

Risk Analysis

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Contents

Purpose

The purpose of the risk analysis is to evaluate hazards, harm consequences, and methods to control the risks.

Scope

The hazard analysis is applied to the EXAMPLE. EXAMPLE is **?????????**

Intended use: ?????????

Applicable Documents

ISO 14971: 2000(E), "Medical devices - Application of risk management to medical devices".

ISO 14971: 2000/Amd. 1:2003(E), Amendment 1: Rational for requirements

Definitions and Acronyms

- ISO 14971 Definitions applies.
- **risk:** combination of the probability of occurrence of harm and the severity of that harm.
- **hazard:** potential source of harm.
- **harm:** physical injury or damage to the health of people, or damage to property or environment.
- **safety:** freedom from unacceptable risk.
- **L.O.C.** Level of concern (Minor, Moderate, High)
- **N.A** Not applicable.
- **Inherent safe design:** Safety is assured by design considerations.
- **residual risk:** risk remains after protective measures have been taken.
- **risk management:** systematic application of management policies, procedures and practices to the tasks of analysis, evaluation and controlling risk.

Option to reduce a risk:

a. Inherent safety by design.

b. Protective measures in the medical device.

c. Protective measures in the manufacturing process.

d. Information for safety.

1. Energy hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

2. Biological hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

3. Mechanical hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

4. Environmental hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

5. Incorrect output hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

All other hazards as defined in ISO 14971, Annex D, Paragraph D.5 (Incorrect output hazards), are not applicable.

6. Use / Operating hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

7. Functional failure (Single fault condition) , Maintenance and Ageing hazards

Type of hazard	Risk	L.O.C	Necessity of risk reduction	Method of risk control	Type of Residual risk	Control of residual risk	Probability of risk after implement

RISK MANAGEMENT PLAN

Safety design verification

Safety tests

Safety management in production.
- **Special processes and Process Qualification**
- **Safety related tests.**
- **Safety related production requirements.**
- **Personnel Qualification.**
- **Environmental conditions.**
- **Cleaning.**

Safety Critical Parts/Components.

Safety management in service