**About this bonus resource from Greenlight Guru:**

* This template includes sections for a thorough Risk Management Plan.
* Green text in brackets shall be replaced with appropriate information.
* Blue text in brackets refers to Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) specific concepts and shall be replaced with appropriate information.
* The signature page can be removed in the event the plan is routed for review and approval within [Greenlight Guru’s Risk Management Software](http://www.greenlight.guru/risk-management-software).
* Remove this section of text before publishing the plan.

**Written by:**

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**Name, Job Title Date**

**Approved by:**

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**Name, Job Title Date**

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**Name, Customer Date**

1. **PURPOSE**

The purpose of the Risk Management Plan protocol is to define the risk management activities planned during the product development process for [insert product].

1. **SCOPE**

The scope of the risk management plan relates to the activities and documentation pertaining to the product risks. The scope of risk management is limited to [insert product], its interface with other products and components, and use during [list type of use] procedures.

1. **RESPONSIBILITY**

|  |  |
| --- | --- |
| RA/QA | * Establishing and maintaining risk management documentation |
| Project Team | * Participating in risk management activities |
| Risk Manager / Product Development Manager | * Assuring that all risks are identified, documented and mitigated to an acceptable level * Obtaining Executive Management approval for risk management activities * Maintaining the Risk Management File (RMF) |
| Executive Management | * Approval of Risk Management Plan |

1. **BACKGROUND**

4.1

[Provide a brief background on the product. Include Intended use statement. Intended use shall describe how the device is used, overview of procedure / application, who uses the device, duration of use, interfaces, etc. Background shall also include information on foreseeable misuse, characteristics that could impact safety, and any defined limits of the products.]

4.2

[For Software as a Medical Device, determine the initial software safety classification per IEC 62304:2006/A1:2015.

The software safety classes shall initially be assigned based on severity as follows:

* Class A – No injury or damage to health is possible
* Class B – Non-serious injury is possible
* Class C – Death or Serious Injury is possible

The manufacturer shall document the software safety class of each software item if that class is different from the class of the software items from which it was created by decomposition.]

1. **RISK MANAGEMENT PLAN**

The risk management activities coincide with the product development and design control process (refer Design & Development Procedure and Risk Management Procedure).

**Table 1 - Risk Management Deliverables by Project Phase**

| **Project Phase** | **Risk Management Deliverables** |
| --- | --- |
| Planning | Risk Management Plan |
| User Needs | System Risk Analysis (hazard identification & source identification) |
| Design Input | System Risk Analysis (hazard identification & source identification) |
| Design Output | * System Risk Evaluation * Risk Assessment (product & process) |
| Design Verification | * Risk Control * Residual Risk Acceptance |
| Design Validation | * Risk Control * Residual Risk Acceptance * Risk Management Report |
| Market Release | * Production & Post-Production Risk Management * Revised Risk Management Report |

Risk management deliverables are reviewed and approved during design reviews for each project phase. ISO 14971:2019 and/or [EU MDR 2017/745 / IVDR 2017/746] for devices entering the EU shall be used for instructions and as guidelines during risk management documentation. Refer to Risk Management Procedure for the company process.

Risk is defined as the combination of occurrence of harm and the severity of that harm. In order to estimate risks of hazardous situations relating to [insert product], severity of harm and probability of occurrence of harm are estimated according to the tables below.

**Table 2 - Severity Table**

| **Severity Rating** | **Description** |
| --- | --- |
| Critical | Loss of limb; life-threatening injury |
| Major | Severe, long-term injury; potential disability |
| Serious | Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation) |
| Minor | Slight customer inconvenience; little to no effect on product performance, non-vital fault |
| Negligible | No or negligible risk to patient |

**Table 3 - Probability Tables**

|  |  |
| --- | --- |
| **Probability Rating** | **Description** |
| Frequent | 1 in 100 |
| Probable | 1 in 1,000 |
| Occasional | 1 in 10,000 |
| Remote | 1 in 100,000 |
| Improbable | 1 in 1,000,000 |

*Risk level is determined based on probability and severity estimates.*

**Table 4 - Risk Estimation**

| Frequent | **LOW** | **MEDIUM** | **HIGH** | **HIGH** | **HIGH** |
| --- | --- | --- | --- | --- | --- |
| Probable | **LOW** | **MEDIUM** | **MEDIUM** | **HIGH** | **HIGH** |
| Occasional | **LOW** | **LOW** | **MEDIUM** | **MEDIUM** | **HIGH** |
| Remote | **LOW** | **LOW** | **LOW** | **MEDIUM** | **HIGH** |
| Improbable | **LOW** | **LOW** | **LOW** | **LOW** | **MEDIUM** |
|  | Negligible | Minor | Serious | Major | Critical |

Risks for [insert product] are identified as LOW, MEDIUM, or HIGH.

A documented benefit-risk analysis is required for risks in the [list risk level(s)] to be accepted.

Risks in the [list acceptable risk level(s)] shall be acceptable.

Risks in the [list unacceptable risk level(s)] are unacceptable and require risk reduction.

All risks determined unacceptable are to be reduced prior to going to market.

Summary of individual risks and evaluation of overall risk acceptability will be documented in the Risk Management Report.

Activities related to production and post-production risk information will be documented in Risk Management Report.