1. **SCOPE OF PLAN**

This Risk Management Plan applies to the <INSERT PRODUCT HERE>. This plan identifies the risk management activities and responsibilities required for the project, from the design phase through market release, per SOP-XX, *Design Control*.

A risk management process is in place to provide a system for risk management; to identify the hazards associated with medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. This process is documented in SOP-XX, *Risk Management*.

The development team will identify the hazards posed by the devices, estimate the risks of the hazard, the likelihood of occurrence, evaluation/mitigation of the risks and verification of the effectiveness of any mitigation by process or product validation.

At market release, the risk management plan will be reviewed and updated as required to assure the appropriate measures are in place for collecting on-going post-production information about the performance of the product.

1. **ASSIGNMENT OF RESPONSIBILITIES AND AUTHORITIES**

<LIST YOUR PLANNED RISK MANAGEMENT ACTIVITIES HERE, THE PHASE REQUIRED TO BE INITIATED AND/OR UPDATED, AND THE RESPONSIBLE INDIVIDUAL FOR EACH. PROVIDING THIS DETAIL ALLOWS CHANGES TO BE DOCUMENTED BY UPDATING THIS RISK MANAGEMENT PLAN ONLY, INSTEAD OF THE PROJECT PLAN WHICH IS TYPICALLY UPDATED AT THE END OF EACH PHASE>

1. **REVIEW OF RISK MANAGEMENT ACTIVITIES**

Each design phase has one or more completed or updated risk management document presented as part of the review. A Risk Management Report will be created for <PRODUCT NAME> to document a final review of the aggregate risk management documents, risk acceptability, and residual risk.

1. **CRITERIA FOR RISK ACCEPTABILITY**

The risk acceptability criteria for the risk management deliverables for this product are planned to correspond to those contained in SOP-XX. Alternative methods, rankings and acceptability criteria may be developed if required. SOP-XX describes the approval requirements for these deviations.

1. **VERIFICATION ACTIVITIES**

Design verification, validation or assessment activities for the <PRODUCT NAME>will include, at minimum:<EDIT AS APPROPRIATE FOR YOUR PRODUCT REQUIREMENTS>

* Design verification testing
* Design validation testing
* Biocompatibility testing
* Product shelf life testing
* Shipping/packaging integrity testing
* Process validation

Note: Each of these items is defined in SOP-XX. The Project Plan (DR####) lists specific verification, validation, and assessment activities for the project. The completed documents are listed in the DHF Index for the products.

1. **POST-PRODUCTION INFORMATION**

SOP-XX *Feedback* provides the process for routine gathering and analyzing of post-production information. Use of post-production information for monitoring and evaluation of product risk is described in SOP-XX *Risk Management*. Sources of data include product complaints, from CAPAs, internal audits or NCRs. The risk management report will list specific concerns or risks and provide for the collection of any additional post-production information required to monitor the risk of the device. The risk management report is reviewed, at minimum, prior to each Management Review.

1. **REFERENCES**
   1. <List Project Plan>
   2. P-1-1 Document Control
   3. P-7-1 Management Review
   4. P-9-4 Risk Management
   5. P-9-1 Design Control
   6. P-16-1 Feedback
2. **REVIEW AND UPDATE OF RISK MANAGEMENT PLAN**

This plan may be revised during the course of the project but at a minimum it shall be reviewed at each design review. At the conclusion of Phase IV, the Risk Management Report will become the living document to document the ongoing life of the device, changes, and updates to the risk profile.