**Risk Management Plan**

**Product Name: *product***

**Table of Contents**

[1 Purpose 3](#_Toc38471194)

[2 Scope of the Plan 3](#_Toc38471195)

[2.1 Product Description 3](#_Toc38471196)

[2.2 Product Life Cycle Phases 3](#_Toc38471197)

[3 References/Forms 3](#_Toc38471198)

[4 Definitions 3](#_Toc38471199)

[5 Responsibilities and Authorities 3](#_Toc38471200)

[6 Risk Management Activities 4](#_Toc38471201)

[6.1 Essential Performance 4](#_Toc38471202)

[6.2 Planned Risk Management Techniques 4](#_Toc38471203)

[7 Product Life Cycle Mapping 5](#_Toc38471204)

[*7.1.1* *Phase 1 – Definition & Planning* 5](#_Toc38471205)

[*7.1.2* *Phase 2 – Design & Development* 5](#_Toc38471206)

[*7.1.3* *Phase 3 – Verification & Validation* 5](#_Toc38471207)

[*7.1.4* *Phase 4 – Commercialization and Production & Post-Production* 5](#_Toc38471208)

[8 Risk Management Review 5](#_Toc38471209)

[9 Criteria for Risk Acceptability 6](#_Toc38471210)

[9.1 Individual Risks: Risk Evaluation Tables 6](#_Toc38471211)

[9.1.1 Severity Ranking Table 7](#_Toc38471212)

[9.1.2 Likelihood Ranking Table 7](#_Toc38471213)

[9.2 Overall Residual Risk 8](#_Toc38471214)

[10 Risk Control Verification 8](#_Toc38471215)

[11 Production and Post Production Information 8](#_Toc38471216)

[*11.1* *Methods of Obtaining Production and Post-Production Information* 8](#_Toc38471217)

[*11.2* *Review Interval* 9](#_Toc38471218)

[11.3 *Update to Risk Management* 9](#_Toc38471219)

[12 Revision History 10](#_Toc38471220)

[13 Approvals 10](#_Toc38471221)

# Purpose

The purpose of this document is to specify the plan for the risk management activities for the Ethiopia mechanical “bridge” ventilator device.

# Scope of the Plan

## Product Description

This plan applies to the Ethiopia mechanical “bridge” ventilator device.

The Ethiopia mechanical “bridge” ventilator will address the shortage of ventilators by providing a “recipe” to rapidly manufacture a low-cost mechanical ventilator that meets minimum clinical and performance specifications outlined by MHRA without compromising safety and efficiency. Ethiopia mechanical “bridge” ventilator will be compatible with existing manual resuscitator bags, and clinicians can control key ventilatory parameters.

## Product Life Cycle Phases

This Risk Management plan appliesto the entire product lifecycle. Section 7 maps elements of the risk management process to the product lifecycle for the product under consideration.

# References/Forms

*QS00XXX: SOP Risk Management, Rev. X*

*ISO 14971:2019 : Medical Devices - Application of Risk Management to Medical Devices,*

# Definitions

DFMEA – Design Failure Mode and Effects Analysis

PFMEA – Process Failure Mode and Effects Analysis

SFMEA - System Failure Mode and Effects Analysis

# Responsibilities and Authorities

The table below describes the roles and responsibilities of the Risk Management Plan. Refer to the project Plan (NPD XXXXX) for individual role assignments.

| **Role** | **Responsibilities** |
| --- | --- |
| Systems Engineer | Principal author and approver of product Risk Management Plan, Risk Assessment and Control, Risk Management Report and System DFMEA. |
| QA/RA | Review and approve all Risk Management File documents including the product Risk Management Plan, Risk Assessment and Control, Risk Management Report, System DFMEA and individual risk benefit analyses. |
| Design Engineer | Expert input in developing the Risk Management deliverables specifically risk control measures. Review and approve the product Risk Management Plan, Risk Assessment and Control, Risk Management Report and System DFMEA.  Principal author and approver of Module/Component DFMEA. |
| Manufacturing Engineer | Expert providing input to the Risk Management activities.  Review and Approve the product Risk Management Plan and Risk Assessment and Control. |
| Product Safety Committee | Review and approve (by signature of the chairman or designee) product Risk Management Plan and the Overall Residual Risk in the Risk Management Report. |
| Test Engineer | Leads the verification effort. |
| Clinical Team Member(s) | Expert providing clinical input on risk assessments and control measures, and risk benefit analysis. |
| Codes & Standards Engineer | Review and provide input to ensure risk assessment, risk control measures and control measure verification are in accordance with the latest C&S requirements. |
| Service Team Member(s) | Expert providing input to the Risk Management activities. |

# Risk Management Activities

## Essential Performance

Essential Performance will be identified. Essential performance, for this product, is defined as any performance necessary to achieve freedom from unacceptable risk. This is further defined to be any RA&C line item which is unacceptable before mitigation **and** is not basic safety and these items will be listed in the Risk Management Report.

## Planned Risk Management Techniques

The risk management process will use the following risk analysis techniques to identify risks.

* Risk Assessment and Control (RA&C)
* Design Failure Mode and Effects Analysis (DFMEA)
  + System DFMEA
  + Module DFMEA for the following modules: TBD
  + Component DFMEA for the following components:TBD
* Process Failure Mode and Effects Analysis (PFMEA)
* Software Hazard Analysis

# Product Life Cycle Mapping

The following describes the planned risk management activities for each of the product lifecycle phases as defined in the Product Development Process SOP.

### Phase 1 – Planning

1. Complete Risk Management Plan
2. Complete Usability Engineering Plan

### Phase 2 – User Needs

1. Start Risk Assessment based on use cases and publicly known hazardous situations
2. Start System DFMEA based on functions

### Phase 3 – Design Input

1. Perform Risk Assessment through Risk Evaluation & Mitigations
2. Perform System DFMEA through Risk Evaluation & Mitigations
3. Start DFMEA(s) (and other Risk Analysis Techniques identified in section 6.1)
4. Start PFMEA(s)

### Phase 4– Design Output

1. Complete Risk Assessment
2. Complete System DFMEA
3. Complete DFMEA(s) (and other Risk Analysis Techniques identified in section 6.1)
4. Complete PFMEA(s)
5. Write Verification Scripts for Risk Controls

### Phase 5 – Verification & Validation

1. Execute Verification Scripts for Risk Control Measures
2. Report Verification Results
3. Update System DFMEA with Results References
4. Update PFMEA(s)
5. Complete Risk Management Report

### Phase 6 – Design Transfer

1. Evaluate complaints, production and post-production surveillance information, and proposed changes to the product
2. Update PFMEA(s)
3. Repeat risk management activities as appropriate and update the Risk Management File.

# Risk Management Review

The following Risk Management Reviews will be conducted:

|  |  |  |
| --- | --- | --- |
| **Review** | **Phase** | **Team** |
| Risk Management Plan | Planning | Product Safety Committee |
| Risk Management Report | Verification and Validation | Product Safety Committee |
| Updated Risk Management Report | Post Commercialization | Product Safety Committee |

# Criteria for Risk Acceptability

## Individual Risks: Risk Evaluation Tables

The criteria for acceptability of individual risks are defined in Table 1: Risk Evaluation Table.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Table 1. Risk Evaluation Table | | | | | | | |
|  | | | Severity of Harm | | | | |
| Negligible | Minor Injury | Moderate Injury | Critical | Catastrophic |
| 1 | 2 | 3 | 4 | 5 |
| Likelihood of Harm | Improbable | 1 | ALAP  Benefit>Risk | ALAP  Benefit>Risk | ALAP  Benefit>Risk | ALAP  Benefit>Risk | ALAP  Benefit>Risk |
| Unlikely | 2 | ALAP  Benefit>Risk | ALAP  Benefit>Risk | Investigate  R/B to be determined | Investigate  R/B to be determined | Unacceptable  R/B to be determined |
| Remote | 3 | ALAP  Benefit>Risk | Investigate  R/B to be determined | Investigate  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined |
| Occasional | 4 | ALAP  Benefit>Risk | Investigate  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined |
| Frequent | 5 | Investigate  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined | Unacceptable  R/B to be determined |

1. All risks shall be reduced as low as possible within state of the art through inherently safe design and construction, protective measures in the device or its manufacture, and provision of validated information for safety.
2. Risks are judged to be acceptable only after they are reduced (mitigated) as far as possible with given technology constraints and standards of care and a risk/benefit analysis confirms the benefits outweigh the risk.
3. Risks that are initially judged to be Unacceptable must be reduced (mitigated) to be acceptable.
4. New risks arising from risk control measures shall be documented and addressed in the product Risk Assessment and Control document.

### Severity Ranking Table

The following will be used to classify the severity of potential harm.

|  |  | Table 2: Severity Ranking |
| --- | --- | --- |
| Ranking | Harm | Criteria: Severity of Harm |
| 1 | Negligible | The hazard could result in a temporary discomfort or inconvenience |
| 2 | Minor Injury | The hazard could result in a reversible non-serious injury to the patient and/or operator where the injury doesn't require medical intervention (e.g., laceration, bruise or contusion). |
| 3 | Moderate Injury | The hazard could result in a reversible non-serious injury to the patient and/or operator where the injury requires medical intervention (e.g., laceration requiring stitches). |
| 4 | Critical | An illness or injury, even if temporary in nature, that results in permanent impairment of a body function or permanent damage to a body structure, or a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure. |
| 5 | Catastrophic | An illness or injury that results in patient death. |

### Likelihood Ranking Table

The following table will be used to rate the likelihood of harm resulting from the hazardous situation.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Table 3: Likelihood Ranking |  |
| Ranking | Likelihood Ranking | Criteria: Likelihood of Harm | Objective Range\* |
| 1 | Improbable | Harm is extremely unlikely, and it can be assumed that the harm may never be experienced | **Improbable** X < 1/ 1,000,000 |
| 2 | Unlikely | Harm is very unlikely but possible to occur during the life of a product. | **Unlikely** 1/1,000,000 ≤ X < 1/100,000 |
| 3 | Remote | Harm is not anticipated, but may occur during the life of a product | **Remote** 1/100,000 ≤ X < 1/10,000 |
| 4 | Occasional | Harm is likely to occur sometime during the life of a product | **Occasional** 1/10,000 ≤ X < 1/1,0001 |
| 5 | Frequent | Harm is likely to occur multiple times during the life of a product. | **Frequent** 1/1000 ≤ X |

Note: The “Objective Range” is to be used to rate the likelihood of Harm only if sufficient data is available to make such a determination. The likelihood of harm is calculated by dividing the number of known occurrences by the number of Patient Experiences. If the likelihood of harm cannot be estimated (either quantitatively or qualitatively), a likelihood of “frequent” shall be used.

## Overall Residual Risk

The criteria for the acceptability of the overall residual risk of the product include:

* + 1. No individual risks fall in the unacceptable region of the risk evaluation table in Section 9.1.
    2. For all risks in the investigate region of the risk evaluation table in Section 9, individual risk benefit analysis concludes the benefits outweigh the risk.
    3. Overall Risk/Benefit analysis determined the medical benefits of the product outweigh the overall residual risk.
    4. Approval by the Product Safety Committee, after reviewing the combined impact of the individual residual risks on the product.

# Risk Control Verification

1. Risk control measures must be recorded as Design Requirements,
2. Implementation of each risk control measure will be verified during design verification activities.
3. The effectiveness of each risk control measure will be verified. The verification of effectiveness can include validation activities.
4. The verification of the risk control measure(s) will be documented in the applicable verification trace summary and traceable to the control measure implemented. The verification trace summary shall be included in the risk management file.

# Production and Post Production Information

After the product design has been completed and the medical device has been manufactured,

information and data about the product will be continuously monitored and, periodically

reviewed and analyzed to determine changes in or impact on risks or

risk control effectiveness.

## Methods of Obtaining Production and Post-Production Information

Methods for obtaining Production and Post-production information are listed in Table 4

**Table 4: Methods of Obtaining Production and Post-Production Information**

|  |  |  |  |
| --- | --- | --- | --- |
| **Source** | **Data / Information & Mechanism** | **Required Actions** | **Responsible** |
| Production Information | Monitoring of Production Quality,  Quality Trending |  |  |
| Post Market Surveillance (Complaints, MDRs) **MDRs)** | Complaint Management,  Medical Device Reporting,  Complaint Processing  Post Market Surveillance Trending Plan |  |  |
| Service & Repair Data | Complaint Processing,  Close Contact with Alleged Complaint. |  |  |
| CAPAs | Corrective and Preventive Action Process |  |  |
| Field Corrective Actions & HHEs | Field Action Process |  |  |
| Publicly available info about similar devices | FDA MAUDE database available on FDA website. |  |  |
| New or revised regulations, Standards | Engineering Codes and Standards |  |  |
| Changes in Customer Usage /  Usability / Standards of Care | Customer Needs Definition, |  |  |

## Review Interval

Production and Post-Production information Collected in 11.1 shall be reviewed at an interval of time not to exceed 1 year, to evaluate the performance of the product for potential safety issues, including previously unidentified hazards, acceptability of estimated risks, and the validity of the risk review*.*

## Update to Risk Management

If any issues are identified in the information review, then elements of the risk management process are repeated with updates placed in the risk management file. If the Overall Residual Risk is impacted, the risk management report is updated and presented to the Product Safety Committee for approval.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Level** | **Description** | **Author** | **Date** |
| 0 | Initial Release |  |  |

# Approvals

Signature approval indicates the content of this risk management plan has been reviewed to ensure that incomplete, ambiguous and conflicting items have been resolved.

|  |  |  |
| --- | --- | --- |
| **APPROVALS** | | |
| **Title** | **Name and Signature** | **Date** |
| Core Team Leader |  |  |
| Printed Name → |  |  |
| Systems Engineer |  |  |
| Printed Name → |  |  |
| Design Engineer |  |  |
| Printed Name → |  |  |
| Manufacturing Engineer  Printed Name → |  |  |
|  |  |
| QA/RA |  |  |
| Printed Name → |  |  |
| Product Safety Committee |  |  |
| Printed Name → |  |  |

# 