Title:	Risk Management Procedure	**Document No.:**	YGD 0402
Effective:	01/11/2022	**Revision:**	2
Revised By:	Syamsida	**Approved By:**	Punitha

1.0 OBJECTIVE

To establish, document, maintain and monitor effectiveness of the control requirement for identifying the hazards associated with medical examination gloves.

2.0 SCOPE

This procedure apply to Medical Examination gloves.

3.0 REFERENCE

ISO 14971(current revision) – Medical devices – Application of risk management to medical devices
Quality Manual
MDSAP Standard
ISO 13485:2016
ISO 9001:2015
Control of Non-conforming Product and Materials – YTY 1301
Control of Non-conforming Product and Materials – GPL 1413
Control of Non-conforming Product and Materials – YTA 1413
Control of Non-conforming Product and Materials – GP 1413
Corrective Action Procedure – YGD 1402
Customer Complaint Procedure – YGD 1401

4.0 DEFINITION

Risk	-	Combination of the likelihood and consequences(s) of a specified hazardous event occurring.
Risk Assessment	-	Overall process of establishing the magnitude of risk and deciding whether or not the risk is tolerable
Tolerable Risk	-	Risk that has been reduced to a level that can be endured by the organization having regard to its legal obligations and its own policy
Hazards	-	Potential source of harm.

5.0 RESPONSIBILITY

5.1 Top Management ensures safety of customer and end user against the hazards/risk of medical examination gloves.

5.2 DC/RA Executive shall be responsible for drafting the file and report. The hazard identification, rating of the severity, occurrence and detection shall be done in consultation with the concerned functions. Guidance shall be taken from QA Manager/ Senior Manager- QA/ RA.

5.3 Senior Manager QA or Senior Manager RA shall approve the Risk Management File.

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6.0 PROCEDURE

6.1 RISK MANAGEMENT PROCESS FLOW CHART

Risk Management Plan

- Scope of Plan
  - Identify the device
  - Life cycle phases for which the each element of the plan is applicable
- Team members and their responsibilities
- Requirements of review of risk management activities
- Criteria for risk acceptability
- Method to evaluate the overall residual risk
- Verification activities
- Collection and review of relevant production and post-production information

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Risk Analysis

- Identify intended use and reasonably foreseeable misuse
- Identify hazards and hazards situation
- Identification of characteristic related to safety
- Use Failure Mode and Effect Analysis (FMEA)

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Risk Evaluation

- Use criteria of risk acceptability, to decide the residual risk.

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Risk Control

- Risk Control option analysis – weigh out options to control the risk
- Implement the risk control measure.
- Evaluate the residual risk after the control measure is implemented.
- Benefit-risk analysis – gather and review data and literature to determine if the benefit of the intended use outweigh the residual risk
- Risks arising from risk control measures
- Completeness of risk control – risks from all identified hazards have been considered.

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Evaluation of overall residual risk acceptability

- Evaluate the overall residual risk after all risk control measures is implemented and verified

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Risk management review

The risk management process is review to ensure that;

- Risk management plan has been implemented
- The overall residual risk is acceptable

Appropriate methods are in place to obtain post-production information

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Production and post-production information.

- Collect and review of information during production and post-production stage

6.2 RISK MANAGEMENT PROCESS

6.2.1 YTY shall establish and maintain a process for identifying hazards associated with a medical device, estimating and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This process shall be documented and shall include the following elements.

6.2.1.1 Risk Analysis
6.2.1.2 Risk Evaluation
6.2.1.3 Risk Control
6.2.1.4 Production & Post-Production Information
6.2.1.5 Overall residual risk evaluation

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Where a documented product design/development process exists, it shall incorporate the appropriate parts of the risk management process.

6.3 MANAGEMENT RESPONSIBILITIES

6.3.1 YTY shall;

6.3.1.1 Define the policy for determining acceptable risk, taking into account relevant international Standards, and national or regional regulations.
6.3.1.2 Ensure the provision of adequate resources
6.3.1.3 Ensure the assignment of trained personnel (see 6.4) for management, performance of work and assessment activities and
6.3.1.4 Review the results of risk management activities at defined intervals to ensure continuing suitability and the effectiveness ofthe risk management process.

The above shall be documented in the risk management file.

The review of the Risk Management activities shall include the responsible individuals or function listed in below table.

Knowledge and experience	Personnel
Medical Device Risk Management Process	Quality Assurance and Regulatory Affairs
Design	R&D
Manufacturing Process	Production
Sources of material	Purchasing
Clinical evaluation methodology and requirements	Quality Assurance and Regulatory Affairs
Regulatory requirements pertaining to safety and risk management in countries/regions where the medical device is intended to be marketed	Regulatory Affairs
Quality Management System and quality practices	Quality Assurance/ DC
Hazards and risk control measure in packaging, storage, handling	Packing
Customer complaints and adverse event reporting, PMS	QA/ RA

6.4 QUALIFICATION OF PERSONNEL

6.4.1 YTY shall ensure that those performing risk management tasks include persons with knowledge and experience appropriate to the tasks assigned to

them. This shall include, where appropriate, knowledge and experience of the medical device and its use and risk management techniques. Records of the appropriate qualification shall be maintained.

6.5 RISK MANAGEMENT PLAN

6.5.1 For the particular medical device or necessary being considered, YTY shall prepare a risk management plan in accordance with the risk management process. The risk management plan shall be part of the risk management file.

6.5.2 This plan shall include the following:

6.5.2.1 The scope of the plan, identifying and describing the medical device and the life cycle phases for which the plan is applicable;
6.5.2.2 A verification plan;
6.5.2.3 Allocation of responsibilities;
6.5.2.4 Requirement for review of risk management activities;
6.5.2.5 Criteria for risk acceptability.

6.6 RISK MANAGEMENT FILE

6.6.1 For the particular medical device or accessory being considered, the results of all risk management activities shall be recorded and maintained in the risk management file

6.7 RISK ANALYSIS PROCEDURE

6.7.1 Risk analysis, as described in 6.8 to 6.10, shall be performed and the conduct and results of the risk analysis shall be recorded in the risk management file.

6.7.2 In addition to the records required in 6.8 to 6.10, the documentation of the conduct and results of the risk analysis shall include at least the following.

6.7.2.1 A description and identification of the medical device or necessary that was analyzed;
6.7.2.2 Identification of the person(s) and organization which carried out the risk analysis
6.7.2.3 Scope and date of the analysis

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6.7.3 Risk Analysis will be update annually.

6.8 INTENDED USE/ INTENDED PURPOSE AND IDENTIFICATION OF CHARACTERISTICS RELATED TO THE SAFETY OF THE MEDICAL DEVICES

6.8.1 For the particular medical device or necessary being considered, YTY shall describe the intend use/intended purpose and any reasonably misuse. YTY shall list all those qualitative and quantitative characteristics that could affect the safety of the medical device and, where appropriate, their defined limits. These records shall be maintained in the risk management file.

6.9 IDENTIFICATION OF KNOWN OR FORESEEABLE HAZARDS

6.9.1 YTY shall compile a list of known or foreseeable hazards associated with the medical device in both normal and fault conditions. Previously recognized hazards shall be identified. This list shall be maintained in the risk management file.

6.9.2 Foreseeable sequences of events that may result in a hazardous situation

6.10 ESTIMATION OF THE RISK(S) FOR EACH HAZARD

6.10.1 For each identified hazard, the risk(s) in both normal and fault conditions shall be estimated using available information or data. For hazard for which the probability of the occurrence of harm cannot be estimated, a listing of the possible consequences of the hazard of the risk(s) shall be recorded in the risk management file.

6.10.2 Any system used for qualitative categorization of probability estimates or severity levels shall be recorded in the risk management file.

6.10.3 The risk estimation incorporates and analysis of the probability of the occurrence and level of severityto the end user. The possible consequences are listed for the use of risk evaluation and risk control.

6.11 RISK CLASSIFICATION:

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i) Risk Classification for Product FMEA & QMS Processes FMEA

Before implementation of Risk Control Measures

Risk index		Risk Classification	Acceptance guidelines
High	RC	Unacceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	RB	Unacceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Low	RA	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

Risk Matrix for before implementation of Risk Control Measures

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
O5	O5*S1(RC)	O5*S2(RC)	O5*S3(RC)	O5*S4(RC)	O5*S5(RC)
O4	O4*S1(RC)	O4*S2(RC)	O4*S3(RC)	O4*S4(RC)	O4*S5(RC)
O3	O3*S1(RB)	O3*S2(RB)	O3*S3(RC)	O3*S4(RC)	O3*S5(RC)
O2	O2*S1(RA)	O2*S2(RB)	O2*S3(RB)	O2*S4(RC)	O2*S5(RC)
O1	O1*S1(RA)	O1*S2R(RA)	O1*S3(RB)	O1*S4(RB)	O1*S5(RB)

Not Acceptable Region (NA) | Acceptable region (A)

6.12 RISK EVALUATION

6.12.1 For each identified hazard, YTY shall decide, using the criteria defined in the risk management plan, whether risk(s) is so low that risk reduction need not be pursued. In this case, the requirement given in 6.2 to 6.6 do not apply for this hazard (i.e. proceed to 6.7). The results of this risk evaluation shall be recorded in the risk management file.

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6.13 RISK CONTROL

6.13.1 Option analysis

YTY shall identify risk control measure(s) that are appropriate or reducing the risk(s) to an acceptable level Risk control shall consist of an integrated approach in which YTY shall use one or more of the following in the priority listed:

6.13.1.1 inherent safety by design

6.13.1.2 protective measure in the medical device itself or in themanufacturing process

6.13.1.3 information for safety

6.13.2 The risk control measure selected shall be recorded in the risk management file.

6.13.3 If, during option analysis, YTY shall conduct a benefit-risk analysis of the residual risk (see 6.15); otherwise, YTY shall proceed to implement the selected risk control measures.

6.14 IMPLEMENTATION OF RISK CONTROL MEASURE(S)

6.14.1 YTY shall implement the risk control measure(s) selected in 6.12.2. The measure(s) used to control the risks shall be recorded in the management file.

6.14.2 The effectiveness of the risk control measures shall be verified and the results of the verification shall be recorded in the risk management file.

6.14.3 Implementation of the risk control measures shall be verified. This verification shall also be recorded in the risk management file.

6.14.4 After implementing Risk Control Measures for Product FMEA & QMS Processes FMEA

Risk index		Risk Classification	Acceptance guidelines
High	RC	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	RB	Conditionally Acceptable based on Benefit-Risk Analysis (CA)	All necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region. Based on the risk/benefit analysis all the residual risks are disclosed by providing information on safety in the form of symbol, precaution, warnings and cautions in IFU & Label.
Low	RA	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

After implementing Risk Control Measures for Product FMEA & QMS Processes FMEA

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
O5	O5*S1(RC)	O5*S2(RC)	O5*S3(RC)	O5*S4(RC)	O5*S5(RC)
O4	O4*S1(RC)	O4*S2(RC)	O4*S3(RC)	O4*S4(RC)	O4*S5(RC)
O3	O3*S1(RB)	O3*S2(RB)	O3*S3(RC)	O3*S4(RC)	O3*S5(RC)
O2	O2*S1(RA)	O2*S2(RB)	O2*S3(RB)	O2*S4(RC)	O2*S5(RC)
O1	O1*S1(RA)	O1*S2(RA)	O1*S3(RB)	O1*S4(RB)	O1*S5(RB)

Not Acceptable Region (NA)	Acceptable after Risk Benefit Analysis (CA)	Acceptable region (A)

6.15RESIDUAL RISK EVALUATION

6.15.1 Any residual risk that remain after the risk control measure(s) are applied shall be evaluated using the criteria defined in the risk management plan.The results of this evaluation shall be recorded in the risk management file.

6.15.2 If the residual risk does not meet these criteria, further risk control measuresshall be applied (see 6.12).

6.15.3 If the residual risk is judged acceptable, then all relevant information necessary to explain the residual risk(s) shall be placed in the appropriated accompanying documents supplied by YTY.

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6.16BENEFIT-RISK ANALYSIS

6.16.1 If the residual is judged unacceptable using the criteria established in the risk management plan and further risk control is impractical, YTY shall gather and review data and literature on the medical benefits of the intended use/intended purpose to determine if they outweigh the residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the residual risk, then the risk remains unacceptable. If the medical benefits outweigh the residual risk, then proceed to 6.16. Relevant information necessary to explain the residual risk shall be placed in the appropriate accompanying documents supplied by YTY. The results of this evaluation shall be recorded in the management file.

6.16.2 Criteria for Risk Acceptability

After Evaluation of Benefit-Risk Analysis for Product FMEA & QMS Processes FMEA

Risk index		Risk Classification	Acceptance guidelines
High	RC	Not Acceptable (NA)	Requires risk reduction by implementing necessary and/or possible control measures for reducing/moving the hazards from not acceptable region to acceptable region.
Medium	RB	Conditionally Acceptable based on Benefit-Risk Analysis (CA)	All necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region. Based on the risk/benefit analysis all the residual risks are disclosed by providing information on safety in the form of symbol, precaution, warnings and cautions in IFU & Label.
Low	RA	Acceptable (A)	Directly acceptable. However, all necessary and/or possible control measures are implemented to minimize probability of risk occurrence for reducing/moving the hazards from not acceptable region to acceptable region.

After Evaluation of Benefit-Risk Analysis for Product FMEA & QMS Processes FMEA

Probability of Occurrence	Severity				
	S1	S2	S3	S4	S5
O5	O5*S1(RC)	O5*S2(RC)	O5*S3(RC)	O5*S4(RC)	O5*S5(RC)
O4	O4*S1(RC)	O4*S2(RC)	O4*S3(RC)	O4*S4(RC)	O4*S5(RC)
O3	O3*S1(RB)	O3*S2(RB)	O3*S3(RC)	O3*S4(RC)	O3*S5(RC)
O2	O2*S1(RA)	O2*S2(RB)	O2*S3(RB)	O2*S4(RC)	O2*S5(RC)
O1	O1*S1(RA)	O1*S2(RA)	O1*S3(RB)	O1*S4(RB)	O1*S5(RB)

Not Acceptable Region (NA)	Acceptable region (A)

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6.17OTHER GENERATED HAZARDS

6.17.1 The risk control measures shall be reviewed to identify of other hazards are introduced. If any new hazards are introduced by any risk control measures, the associated risk(s) shall be assessed (See 6.10). The results of this review shall be recorded in the risk management file.

6.18COMPLETENESS OF RISK EVALUATION

6.18.1 YTY shall assure that the risk(s) from all identified hazards have been evaluated. The results of this assessment shall be recorded in the risk management file.

6.19OVERALL RESIDUAL RISK EVALUATION

6.19.1 After all risk control measures have been implemented and verified, YTY shall decide if the overall residual risk posed by the medical device is acceptable in the risk management plan. If the overall residual risk is judged unacceptable using criteria established in the risk management plan, YTY shall gather and review data and literature on the medical benefits of the intended use/intended purpose to determine if they outweigh the overall residual risk. If this evidence does not support the conclusion that the medical benefits outweigh the overall residual risk, then the risk remains unacceptable. The results of the overall residual risk evaluation shall be recorded in the risk management file.

6.20RISK MANAGEMENT REPORT

6.20.1 The results of the risk management process shall be recorded in a risk management report. The risk management report shall provide traceability for each hazard to the risk analysis, the risk evaluation, the implementation and verification of the risk control measures, and the assessment that the residual risk(s) is acceptable. The risk management report shall form part of the risk management file.

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6.21 RISK MANAGEMENT REVIEW

6.21.1 The Risk management report is reviewed for implementation, verification and effectiveness of all the risk control measures.

6.21.2 A systematic review is performed to review the risk management activities as per ISO 14971:2019 requirements. These reviews are carried out in design phase, production phase and post-production phase.

6.21.3 The Risk Management is a living document and shall be review every year if no other changes and when there is a new design.

6.21.4 The design reviews are carried as part of Design & Development Review. The production & post-production phase reviews are carried out as part of the periodic management reviews.

6.22 PRODUCTION AND POST-PRODUCTION INFORMATION

6.22.1 YTY shall establish and maintain a systematic procedure to review information gained about the medical device or similar devices in the production and post- production phase. The information shall be evaluated for possible relevance to safety, especially the following:

i. If previously unrecognized hazards are presents
ii. If the estimated risk(s) arising from a hazards is no longeracceptable;
iii. If the original assessment is otherwise invalidated

6.22.2 If any of the above conditions is satisfied, the results of the evaluation shall be feedback as an input to the risk management process. Information such as past-production information, adverse event, MDR, CAPA, Rework or customer feedback shall be updated to Risk Management Report.

6.22.3 In the light of this safety relevant information, a review of the appropriate steps of risk management process for the medical device shall be considered.If there is a potential that the residual risk(s) or its acceptability has changed,the impact on previously implemented risk control measures shall be evaluated.

6.22.4 Activities for the collection and review of production and post-production information.

The collection and review of production and post-production informationare as per below table. This will be effectively communicated and coordinated between the departments for the review by the responsible person as per clause 3.0.

Data Sources	Information	Department
Production	- Data from monitoring supplier performance/controls - Process monitoring - In-process inspection/testing - Internal/external audits	QA/ IQC/ Purchasing QA Lab QA/DC/RA
Complaint handling	Quantity By customer Reason for complaint Severity of any harm	QA
Risk management	Published adverse event report for similar glove	RA
Clinical activities	Post-Market Clinical Follow-up (PMCF)	RA (not required for Class I)
Market/customer survey	Customer Satisfaction Survey	CC/QA/RA
Media sources	Article in journals/literature	RA

6.22.5 The results of this evaluation shall be recorded in the risk management file

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7.0 RECORDS

Records pertaining to Risk monitoring and measurement shall be maintained and it is subject for continual review and update and retention period be maintained as per YGD 1601 – Records Procedure.

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Revised By:	Syamsida	**Approved By:**	Punitha

Reason for Change

Old Revision	*Current Revision*	*Effective Date*	*Page Affected*	*Revision Description*	*Revised By*	*Approved By*
Nil	0	31/05/2021	All	New Procedure	Syamsida	Punitha
0	1	25/10/2021	Pg. 1 & 6	Revised 3.0 and 6.10.6 clause.	Noraziah	Vengatesh
0	2	01/11/2022	All	Revised 3.0, 5.3 & 6.0 – 6.23	Syamsida	Punitha

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