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บริษัท ศรีตรังโกลฟส์ (ประเทศไทย) จำกัด (มหาชน)
ทะเบียนเลขที่ 0107562000106
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Risk Management Plan

Product: Latex Examination Gloves, Powder Free, Non-Sterile

No.	Risk Management Activities	Person Responsible & Authority
1	Issuing and update Risk Management procedure	QA PRODUCT(GLOVE) MGR
2	Define Risk Management policy	CEO
3	Establishing Risk Management acceptance criteria	CEO
4	Assign R.M. Team	CEO
5	Risk Management Plan	QA PRODUCT(GLOVE) MGR + QMR
6	Risk Analysis - Intended use and reasonably foreseeable misuse - Identification of characteristics related to safety - Identification of hazards and hazardous situations - Estimation of Risk for each hazardous situation	R.M. Team / Small working group
7	Risk Evaluation	R.M. Team / Small working group
8	Risk Control - Risk control option analysis - Implementation of risk control measure - Residual risk evaluation - Benefit-risk analysis - Risks arising from risk control measures - Completeness of risk control	R.M. Team / Small working group
9	Verification of risk control	R.M. Team / Small working group
10	Evaluation of overall residual risk acceptability	R.M. Team / Small working group
11	Risk management review	Senior Assistant of QA PRODUCT(GLOVE) MGR + QA PRODUCT(GLOVE) MGR/ RMT Leader + Senior Assistant of Technical Product Management Manager + R&D Manager + Technical Assurance Manager + Quality System Manager / QMR + CEO
12	Production & Post-Production Information Review	R.M. Team / Small working group
13	Maintain Risk Management File	QA PRODUCT(GLOVE) MGR

Original document is signed in the factory. This version is valid without signature.

Prepared By: Senior Assistant Product Manager (Glove)

_____ _____

Ms. Hataichanok Khemawanit Date

Reviewed by: Product Manager (Glove)

_____ _____

Ms. Sureerat Choosri Date

Approved by: CEO

_____ _____

Ms. Jarinya Jirojkul Date

Risk Analysis RA-002
Version : 01
Date : 15/07/2021
Product type : Latex Examination Gloves, Powder Free , Non sterile
Intended use : A patient examination glove is a disposable device intended for medical purposes that is worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination glove is intended for medical activities except surgery

Risk Evaluation

Type of Hazard	Hazard	Cause of Hazard	Life Cycle	Hazardous Situation	Normal condition/ Infault condition	Harm	Effect on	S	O	RPN	Action	Approach to Reduce Risk	New Risk	Verification of Implementation	Verify of Risk Reduction	Risk-Benefit Analysis	Overall Evaluation
Chemical hazards	Chemical residue	Residual chemicals present in the glove material	Design, Production	Migration of residual substances during application of products	Normal condition	Sensitization/ Irritation reactions on the skin	Patient, User	2	2	4	- Recommendation for Dithiocarbamate warning on the labelling - pH tracking - raw material approval	Warning Production control process follow work instruction	None identified	- QA checking on labeling according to SCT.QA.QP.15.004 Packaging and Labeling Control Procedure 2. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure & SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan 3. Checking on process according to SCT.QA.QP.10.001 Approval of raw material or supplier	1. Labeling with a warning on Dithiocarbamates 2. Raw material pass	-	Acceptable
Chemical hazards	Latex/ Nitrile powdered gloves mixed into latex powder free gloves	Processing error during packing	Production	User does not expect different glove type in the application	Infault condition	Usage difficulty in application	Patient, User	1	0	0	1. Implementation of packing line clearance as part of the packing process 2. Using production cards to identify the products in each manufacturing batch 3. Separating the packing room for each product type; latex powdered, latex powder-free, and nitrile powder-free	Prevention	None identified	Checking the packing line clearance and products to be packed according to SCT.QA.QP.15.001 Packing and Loading Procedure	1. Complaint trend; records of product mix up 2. Internal NC issuing to this matter	-	Acceptable
Chemical hazards	Toxicity of a chemical introduced into/onto the glove	Wrong chemical added into the glove	Design, Production	Migration of wrongly added substances or residues of those substances during application of products	Infault condition	Irritation, Sensitization, Intoxication (mutagenic, cancerogenic, teratogenic)	Patient, User	5	0	0	1. Compounding preparation according to the defined formulation of each product 2. Identification cards with approval status for each chemical used in the compounding area	Prevention	None identified	Checking the compounding preparation according to SHY.CP.WI.09.001 Work Instruction of Compounding Control	1. Internal NC issuing to this matter 2. Identity cards controlled during internal audits	-	Acceptable
Information hazards (Labelling)	Microorganism on the glove (non-sterile)	Unintended usage of examination gloves as surgical gloves	Application	Non-sterile examination gloves used for surgical operations.	Infault condition	Infection of the patient, due to missing sterile condition. Further, high risk to a surgeon, as examination gloves are weaker - higher chance of infection/contamination	Patient, User	5	0	0	Labeling clearly indicates Non-sterile as examination glove	Prevention	None identified	QA checking on labeling according to SCT.QA.QP.15.004 Packaging and Labeling Control Procedure	Existing STGT labeling clearly label as an examination glove	-	Acceptable

Type of Hazard	Hazard	Cause of Hazard	Life Cycle	Hazardous Situation	Normal condition/ Infault condition	Harm	Effect on	S	O	RPN	Action	Approach to Reduce Risk	New Risk	Verification of Implementation	Verify of Risk Reduction	Risk-Benefit Analysis	Overall Evaluation
Information hazards (Labelling)	Inability to trace back the devices completely	Unfit, incomplete information on labeling for tracking purpose.	Design, Production	Defect products cannot be traced back to identify the root cause or established inability to perform FSCA	Infault condition	Potential defects and harm cannot be traced back to the root cause, as traceability is not given.	Patient, User	4	1	4	Checking the lot information on packaging during the process by QC at the in-process and final steps	Prevention	None identified	QC checking the lot information on packaging according to SCT.QA.QP.15.004 Packaging and Labeling Control Procedure & SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan	QC record	-	Acceptable
Information hazards (Warning)	Microorganism on the glove	Unintended usage of the single-use / individual use gloves	Application	Multiple-use of the single-use examination glove	Infault condition	Infection of the patient with contamination from the first use of the device. Potential harm to the user, as a glove is not designed to endure multiple-use	Patient, User	5	0	0	Labeling clearly indicates single-use as an examination glove.	Prevention	None identified	QA checking on labeling according to SCT.QA.QP.15.004 Packaging and Labeling Control Procedure	Existing STGT labeling clearly label as an examination glove for sigle use only	-	Acceptable
Biological hazards	Microorganism and contamination passing through the glove barrier	Pin Hole in the glove	Production	Exchange of contamination/ microorganism by user and patient during application	Infault condition	Infection/contamination of the patient and/or user	Patient, User	5	5	25	1. Improvement and tracking of pinhole rates; Corrective actions on root causes through the established CAPA process 2. Checking and monitoring the hole testing by QC for	Prevention	None identified	1. QC checking the hole on gloves according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan	Existing STGT trend analysis of pinhole rates in production	RBA-003 Rev.01	Acceptable
Biological hazards	Microorganism and contamination passing through the glove barrier	Thin spot, that leads to hole during application	Production	Exchange of contamination/ microorganism by user and patient during application	Infault condition	Infection/contamination of the patient and/or user	Patient, User	5	1	5	1. Improvement and tracking of pinhole rates; Corrective actions on root causes 2. Checking and monitoring the thin spot problem by QC for each manufacturing batch according to the procedures	Prevention	None identified	1. QC checking the thin spot on gloves according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan 2. Improvement and tracking of thin spot rates according to SCT.QA.QP.14.001 Corrective and Preventive Actions Procedure & SCT.QA.QP.19.002 Handling of Complaint Procedure	Existing STGT trend analysis of thin spots rates in production	RBA-003 Rev.01	Acceptable
Biological hazards	Contamination, Infection caused by glove	The glove is contaminated with blood or other body fluids capable of transmitting diseases	Production	Infection during application & handling	Infault condition	Infection/contamination of the patient and/or user	Patient, User	5	1	5	1. Controlling the personal hygiene, GMP rules of production, packing and all related staffs 2. Reporting procedure of all wounds in the production/ packaging areas	Immediate reaction	None identified	Checking the implemtation of personal hygiene, GMP rules in production/ packing areas according to SCT.QA.QP.22.001 Personnel Hygiene Control Procedure	Records of training, accidents and hygiene zones	RBA-002 Rev.01	Acceptable
Biological hazards	Contamination, Infection caused by glove	Embedded, non-sharp foreign object (incl. dirt, insect, hairs) in/on the glove	Production /Storage	Transmission of contamination during application	Infault condition	Inconvenience to temporary discomfort	Patient, User	1	3	3	Controlling the personal hygiene, GMP rules, pest control, cleaning, as well as pre-requisite programs (PRP)	Prevention	None identified	Checking the implemtation of personal hygiene, GMP rules, pest control, cleaning, as well as pre-requisite programs (PRP) according to SCT.QA.QP.22.001 Personnel Hygiene Control Procedure, SCT.QA.QP.22.002 Cleaning Procedure, SCT.QA.QP.22.003 Pest Control Procedure, and SCT.QA.QP.22.004 Pre-Requisite Programs (PRP) Procedure	Records of Hygiene zone plan; pest control results; bioburden tracking	-	Acceptable

Type of Hazard	Hazard	Cause of Hazard	Life Cycle	Hazardous Situation	Normal condition/ Infault condition	Harm	Effect on	S	O	RPN	Action	Approach to Reduce Risk	New Risk	Verification of Implementation	Verify of Risk Reduction	Risk-Benefit Analysis	Overall Evaluation
Biological hazards	Contamination, Infection caused by glove	Fungus, bacteria cultures or viruses on the glove; wrong storage conditions	Production, Storage	Infection during application & handling	Infault condition	Infection/contamination of the patient and/or user	Patient, User	5	1	5	1. Hygiene Control areas; Pest control; Hygiene procedures; Bioburden tracking 2. Storage the gloves as defined areas with proper conditions 3. Verify and ploblem solving.	Prevention	None identified	1. Checking the implemtation of hygiene zone according to SCT.QA.QP.22.002 Cleaning Procedure, SCT.QA.QP.22.003 Pest Control Procedure, and SCT.QA.QP.22.004 Pre-Requisite Programs (PRP) Procedure 2. Gloves storage according to SCT.QA.QP.15.003 Internal Transport and Storage Procedure	1. Records of Hygiene zone plan; Pest control results; bioburden tracking 2. Stabilization of bioburden; adherence to hygiene control rules	RBA-002 Rev.01	Acceptable
Biological hazards	Allergy reaction to natural rubber protein	Proteins from the rubber plant in the final product causes allergy	Application	Natural rubber latex sensitized person has contact to natural rubber products during application	Infault condition	Allergy reaction can range from mild skin reaction to anaphylactic shock, which could cause fatal consequences.	Patient, User	5	1	5	1. Natural Rubber Proteins are leached out of the glove during the process to the highest possible degree. 2. Natural rubber latex warning and symbols shall be placed on all dispenser and user information sheets to warn sensitized persons before usage. 3. Long term developments of further product improvements to lower	Prevention	None identified	1. Protein trends of natural rubber latex products from internal and external testing. 2. Artwork approbations of inhouse brands 3. Improvement projects started in development.	As no cases are known or have been reported in recent years, the measurements are shown effective.	RBA-001 Rev.01	Acceptable
Physical hazards	Physical damage caused by glove	Embedded, sharp metal parts & other solid objects in the glove	Production	Mechanical force applied to the metal piece during application	Infault condition	Injury of body parts examined/treated	Patient, User	2	1	2	Hygiene Control areas; Hygiene procedures	Prevention	None identified	Checking the implemtation of hygiene control according to SCT.QA.QP.22.001 Personnel Hygiene Control Procedure, SCT.QA.QP.22.002 Cleaning Procedure, SCT.QA.QP.22.003 Pest Control Procedure, and SCT.QA.QP.22.004 Pre-Requisite Programs (PRP) Procedure	Records of Hygiene zone plan; Hygiene Control	-	Acceptable
Physical hazards	Visual defect on glove causing disposal	Visual defect (e.g. discoloration) causes suspicion with the user	Production	Gloves cannot be used for the application	Ifault condition	Inability to perform medical procedures	User	1	4	4	1. Controlling the production process according to the procedures and parameters defined 2. Monitoring % visual defect by Production and QC during the production process	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. QC checking the % visual defect according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan	Record of % Visual Defect by Production and QC during production process at in-process and final stages	-	Acceptable

Type of Hazard	Hazard	Cause of Hazard	Life Cycle	Hazardous Situation	Normal condition/ Infault condition	Harm	Effect on	S	O	RPN	Action	Approach to Reduce Risk	New Risk	Verification of Implementation	Verify of Risk Reduction	Risk-Benefit Analysis	Overall Evaluation
Physical hazards	Glove unfit for usage, due to torn appearance	Already torn glove is packed	Production	Gloves cannot be used for the application	Infault condition	Inability to perform medical procedures	User	1	4	4	1. Controlling the production and packing process according to the procedures and parameters defined 2. Monitoring % visual defect by Production and QC during the production process	Prevention	none identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure & SCT.QA.QP.15.001 Packing and Loading Procedure 2. QC checking the % visual defect according to SCT.QA.QP.10.003 In-Process and Final	Record of % Visual Defect by Production and QC during production process at in-process and final stages	-	Acceptable
Physical hazards	Glove unfit for usage, due to torn appearance	Glove is too weak and tears easily	Application	Gloves tears during application and creates the potential for contamination	Infault condition	Infection/contamination of the patient and/or user; glove parts might be lost during application	User	5	3	15	1. Controlling the production process according to the procedures and parameters defined 2. Monitoring % visual defect by Production and QC during production process and monitor the physical properties of glove by Lab	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. QC checking the % visual defect and Lab checking the physical properties of glove according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan	Record of % Visual Defect by Production and QC during production process and % Incontrol of physical properties at in-process and final stages	RBA-003 Rev.01	Acceptable
Physical hazards	Glove unfit for usage, due to coagulation lump	Glove carries a massive lump of rubber	Production	Gloves cannot be used for the application	Infault condition	Inability to perform medical procedures	User	1	4	4	1. Controlling the production process according to the procedures and parameters defined 2. Monitoring % visual defect by Production and QC during production process	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. QC checking the % visual defect according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan	Record of % Visual Defect by Production and QC during production process at in-process and final stages	-	Acceptable
Physical hazards	Gloves not usable, due to stickiness/Slippery	The surface treatment is insufficient; wrong storage conditions	Production, Storage	Gloves cannot be donned without being damaged before application	Infault condition	Inability to perform medical procedures	User	1	3	3	1. Controlling the production process according to the procedures and parameters defined 2. Monitoring % Visual Defect by Production and QC during production process and do real time study of product (Shelf life of product) 3. Storage gloves in	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. QC checking the % visual defect according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan 3. Verification of	1. Record of % Visual Defect by Production and QC during production process at in-process and final stages 2. Real time & accelerated aging study	-	Acceptable
Physical hazards	Glove not fitting in length	Wrong production parameters; shrinkage; wrong storage conditions	Production, Storage	Gloves do not properly cover the wrist area	Infault condition	Inability to perform medical procedures	User	1	2	2	1. Controlling the production process according to the procedures and parameters defined 2. Monitoring % glove length by Production and Lab during production process 3. Storage gloves in suitable temp & humidity	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. Lab checking the % glove length according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan 3. Gloves storage according to SCT.QA.QP.15.003 Internal Transport and Storage Procedure	Record of % glove length by Production and Lab during production process at in-process and final stages	-	Acceptable

Type of Hazard	Hazard	Cause of Hazard	Life Cycle	Hazardous Situation	Normal condition/ Infault condition	Harm	Effect on	S	O	RPN	Action	Approach to Reduce Risk	New Risk	Verification of Implementation	Verify of Risk Reduction	Risk-Benefit Analysis	Overall Evaluation
Physical hazards	Glove not fitting in dimension (Width , thickness , wrong size)	Wrong former used; wrong size packed	Production	Missing tactile sensitivity	Infault condition	Inability to perform medical procedures	User	1	4	4	1. Controlling the production and packing process according to the procedures and parameters defined 2.Line clearance in packing area; Procedures to prevent mixing of size of product; identification cards for each manufacturing batch	Prevention	None identified	1. Checking on process according to SCT.QA.QP.09.001 Production Control Procedure 2. Lab checking the % glove dimension according to SCT.QA.QP.10.003 In-Process and Final Inspection Sampling Plan 3. Checking the packing line clearance and products to be packed according to	1. Record of Size mix up during production process by QC 2. Complaint trend; records of glove size mix up	-	Acceptable

Overall Residual Risk : -

Summary : The outcome of Risk evaluation for this product is acceptable The overall risk for this product is acceptable.

Remark :

Based on the conducted risk analysis for the Latex Powder Free Examination Gloves, Non-Sterile product **(LC01, LO01)**, the all foreseeable risks have been identified and evaluated with respect to the intended application and use of the products.
Thus, it can be determined that the overall residual risk is acceptable when outweighs the benefits from the use of the products

Reference document : SCT.QA.QP.14.003
Document Retention Period : Paper 11 years , Electric Forever

Risk Analysis : RA-002

Version: 01

Date : 15/07/2021

Product type: Latex Examination Gloves, Powder Free , Non sterile

Acceptance matrix before and after mitigations

Acceptance matrix :

Severity

Probability	1	2	3	4	5
0	0	0	0	0	0
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

Remark : Probability : 0 If we never found this.

Acceptable	0-4
Unaccepttable	5-25

Severity

Term	Description	Ranking
Negligible	Inconvenience to temporary discomfort	1
Minor	Result in injury or impairament not requiring	2
Serious	Result in injury or impairament requiring	3
Critical	Result in temporary impairment to serious	4
Catastrophic	Result in permanent impairment to life	5

Probability	Internal Monitoring % In control of related properties	complaint topic per 1,000,000	Ranking
Very unlikely to occur	Never found the defec before through the whole business years of the company	Never found the defec before through the whole business years of the company	0
Improbable	>/= 98%	</= 0.0002	1
Rare	>/= 96%	</= 0.0010	2
Occasional	>/= 94%	</= 0.0033	3
Probable	>/= 90 %	</= 0.0333	4
likely	< 90%	> 0.0333	5

Remark : Probability shall be considered from both of “Internal Monitoring % In-Control of Related Properties” and “Complaint Topics per 1,000,000 Exported Glove Pcs” and chosen the highest-ranking score, if both are applicable.

Reference document : SCT.QA.QP.14.003

Document Retention Period : Paper 11 years , Electric Forever

Risk Analysis : RA-002

Version: 01

Date : 15/07/2021

Product type: Latex Examination Gloves, Powder Free , Non sterile

Analysis by :

Ms.Sureerat Choosri	Product Department
Ms.Nawarat Arunpan	Technical Assurance Department and Assessment Department
Ms.Vanlinee Laohachaiyakul	Product Department
Ms.Sansanee Thepnimit	Research and Development Department
Ms.Sineenat Utanpun	Quality System Department
Mr.Aekasit Kongkeaw	Technical Assurance Department
Mr.Burin Meethip	Technical Assurance Department
Ms.Sutthisa Buamat	Assessment Department
Mr.Nattawut Promthong	Technical Product Management Department
Ms.Hataichanok Khemawanit	Product Department

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Established By: _____ Date: _____

(Ms.Hataichanok Khemawanit)

Position: Senior Asst. Product Manager (Gloves)

Reviewed By: _____ Date: _____

(Ms.Sureerat Choosri)

Position: Product Manager (Gloves)

Approved By: _____ Date: _____

(Ms.Jarinya Jirojkul)

Position: CEO

Reference document : SCT.QA.QP.14.003

Document Retention Period : Paper 11 years , Electric Forever

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Risk management review

Product: Latex Examination Gloves, Powder Free, Non-Sterile

Report#: RMR-LPF-01-001

The risk management team has conducted review on the risk management process. It can be summarized that:

- The risk management plan has been appropriately implemented;
- The overall residual risk is acceptable;
- The production and post-production feedback information have been collected and reviewed at least once a year in accordance with the Risk Management Procedure (SCT.QA.QP.14.003) as well as SCT.QA.QP.19.001 Feedback Procedure

The above statement can be concluded that Latex Examination Gloves, Powder Free, Non-Sterile produced by Sri Trang Gloves (Thailand) Public Company Limited., are safe for patients and users and comply with the applicable national regulations and relevant international standards and regulations.

Original document is signed in the factory. This version is valid without signature.

Prepared by: Senior Assistant Product Manager (Glove)

_____ _____

Ms. Hataichanok Khemawanit Date

Reviewed by: Product Manager (Glove)

_____ _____

Ms. Sureerat Choosri Date

Approved by: CEO

_____ _____

Ms. Jarinya Jirojkul Date