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TECHNICAL DOCUMENTATION

(acc. to MDR (EU) 2017/745 Annex II & III)

Product: Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade

Product Group Code: LO01

Revision: 06

Date: 01 January 2021

PREPARED BY:	APPROVED BY:
Mr. Nattawut Promthong Senior Assistant Technical Product Management	Mr. Daniel Stocker Group of Quality and R&D Manager
SIGNED: *Electronic file is valid without a signature*	SIGNED: *Electronic file is valid without a signature*

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TECHNICAL DOCUMENTATION

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1 Device description and specification

(a) Product or trade name and a general description of the device including its intended purpose and intended users

Product or Trade Name

Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade

Product Group Code

LO01

Legal Manufacturer

Sri Trang Gloves (Thailand) Public Company Limited

10 Soi 10, Phetkasem Road, Hat Yai, Songkhla 90110 Thailand

Manufacturing Facilities

Site 1 (STGT-HY1): 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand

Site 2 (STGT-HY2): 109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand

Site 3 (STGT-HY3): 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand

Site 4 (STGT-HY4): 110/3 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand

Site 5 (STGT-SR): 189 Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160 Thailand

Site 6 (STGT-TG): 85 Moo 6, Kuan Thani, Kantang, Trang 92110 Thailand

European Authorised Representative

Medical Device Safety Service GmbH

Schiffgraben 41, 30175 Hannover, Germany

Table 1: General Description

NO.	Topic	Description
1	Product name	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade
2	Product group code	LO01
3	Product code	LOFSOG LOFBOG
4	Product specification code	LOOOGF-S-EU-M-NS LOOOGF-B-EU-M-NS
5	Type	Single-use disposable examination glove
6	Marking	All information on dispenser box
7	Shape	Ambidextrous
8	Material	Natural rubber latex
9	Inner treatment	Online Chlorination
10	Outer treatment	No treatment
11	Cuff/ surface	Rolled cuff/ Textured at finger tip
12	Color	Pale Yellow, the color may vary due to storage time and conditions.
13	Available sizes	Extra Small (XS) Small (S) Medium (M) Large (L) Extra Large (XL)

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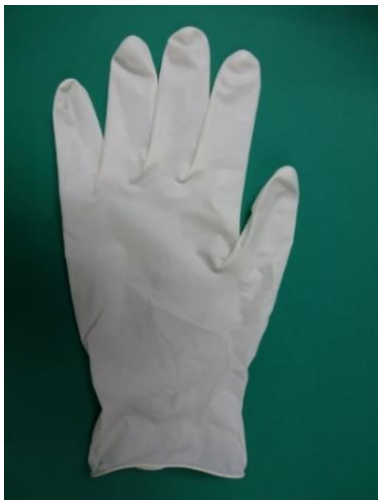
NO.	Topic	Description
14	Photographs	 Figure 1: Photograps of LO01 product

Intended Purpose

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. Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are intended for medical activities except surgery.

Intended Users

Medical personnel, who perform medical examinations, diagnostic and therapeutic procedures, as well as personnel, who work with contaminated medical materials.

(b) The Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability

The Basic UDI-DI of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) is 88591306LO01V9.

The definition is as follows:
88591306: Company Prefix registered number with GS1 represents for Sri Trang Gloves (Thailand) Public Company Limited
LO01: Product Reference as Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01)
V9: Check Character that has been calculated and validated on GS1 website

(c) The intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contraindications, warnings

Intended Patient Population

The intended patient population is for medical personnel, who perform medical examinations, diagnostic and therapeutic procedures, as well as personnel, who work with contaminated medical materials.

Examination gloves are intended for all kind of patients, with the requirement of hygienic medical therapy and/or examination, both superficial skin and natural body orifices. It is not intended for patients, that require surgical procedures. Respective sensitizations and allergy warnings must be respected.

Medical Conditions to be Diagnosed, Treated and/or Monitored

The examination gloves are used in medical or healthcare facilities indoors in a dry place, away from direct sunlight, at recommended temperature from 10 $^{\circ}$C to 30 $^{\circ}$C.
The examination gloves are intended for medical activities except surgery.

Indications

The indications for use of the medical device are the necessity of conduction of medical examinations, diagnostic and therapeutic procedures.

Table 2: Summary of the Indications for Gloving and for Glove Removal

	Indication
Gloves on	1) Before hygienic procedures 2) When anticipating contact with blood or another body fluid, regardless of the existence of sterile conditions and including contact with non-intact skin and mucous membrane 3) Contact with a patient (and his/her immediate surroundings) during contact precautions
Gloves off	1) As soon as gloves are damaged (or non-integrity suspected) 2) When contact with blood, another body fluid, non-intact skin and mucous membrane has occurred and has ended 3) When contact with a single patient and his/her surroundings, or a contaminated body site on a patient has ended 4) When there is an indication for hand hygiene 5) When healthcare facility internal guidelines require the removal of the glove

Contraindications/ Warning

The contraindications/ warning of the examination gloves are as follows:

- For single use only;
- For individual use only;
- It is necessary to perform hygienic treatment of your hands before putting on or changing gloves, as well as after removing the gloves;
- It is necessary to choose the gloves of the right size;
- It is necessary to change the gloves in case of any defect, puncture, damage, contamination, etc.;
- It is necessary to put the gloves on dry hands only;
- Keep in dry condition and avoid the sunlight or other ozone sources;
- The composition of the medical device includes natural rubber latex that may cause an allergic reaction

(d) Principles of operation of the device and its mode of action, scientifically demonstrated if necessary

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. Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are intended for medical activities except surgery.

The operational principles might vary, depending on healthcare facilities and operations done with the product. The usage procedure is self-explanatory and further instructed during the training of healthcare personnel. The general contradictions and warnings apply to all procedures.

(e) The rationale for the qualification of the product as a device

Medical gloves are used to prevent the transmission of disease and provide a safety barrier against contamination. They are typically used during examinations or medical procedures. As such, they are medical devices.

(f) The risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII

Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are medical device, class I.
The product is classified in accordance with Rule 1 and Rule 5 of Annex VIII;

"Rule 1: All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies"
"Rule 5: All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: Class I if they are intened for transient use".

The rationale for classification is shown as table below.

Table 3: Classification Rationale

Classification Rules Acc. to Annex VIII	Applicable (Y/N)	Rationale
Non-invasive devices, Rule 1	Y	The examination gloves are disposable device intended for medical purposes that are worn on the examiners hand or finger to prevent contamination between patient and examiner. Examination gloves are intended for medical activities except surgery and mostly used for external, so it could be determined that the device is non-invasive as class I.
Non-invasive devices, Rule 2	N	The examination gloves are not intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body.
Non-invasive devices, Rule 3	N	The examination gloves are not intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body. Also the examination gloves are not consisted of a substance or a mixture of substances intended to be used in vitro.
Non-invasive devices, Rule 4	N	The examination gloves are not intended for come into contact with injured skin or mucous membrane.
Invasive devices, Rule 5	Y	The examination gloves are also intended for transient use in term of invasive device with respect to body orifices such as gynecologist or dental work.
Invasive devices, Rule 6 – 8	N	The examination gloves are intended for medical activities except surgery, so the device is not classified as surgically invasive devices as well as implantable devices.
Active devices, Rule 9 – 13	N	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, so the device is not classified as active devices.

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Classification Rules Acc. to Annex VIII	Applicable (Y/N)	Rationale
Special rule 14	N	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, so the device is not classified as medicinal product.
Special rule 15	N	The examination gloves are not intended to use for contraception or prevention of the transmission of sexually transmitted diseases.
Special rule 16	N	The examination gloves are not intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses. Also the examination gloves are not intended specifically to be used for disinfecting or sterilizing medical devices.
Special rule 17	N	The examination gloves are not intended specifically for recording of diagnostic images generated by X-ray radiation.
Special rule 18	N	The examination gloves are not manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable.
Special rule 19	N	The examination gloves are not incorporating or consisting of nanomaterial.
Special rule 20	N	The examination gloves are not intended as invasive devices with respect to body orifices to administer medicinal products by inhalation.

Classification Rules Acc. to Annex VIII	Applicable (Y/N)	Rationale
Special rule 21	N	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. The examination gloves are intended for medical activities except surgery, so the device is not composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body.
Special rule 22	N	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, so the device is not classified as active therapeutic devices.

(g) An explanation of any novel features

This requirement is not applicable, as examination gloves are not claimed as novel devices.

(h) A description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it

This requirement is not applicable, as examination gloves are not worn with other accessories or used in combination.

(i) A description or complete list of the various configurations/variants of the device that are intended to be made available on the market

The examination gloves will be packed and made available on the market under form of its packaging.

The package provides protection from the exposure to mechanical and climatic factors during transportation and storage. The package consists of primary and secondary packaging as follows;

Primary packaging or Dispenser box: The gloves are packed into dispenser box. The dispenser box provides protection of gloves from external mechanical damage and makes it possible to determine visually the identification and traceability of the gloves.
Secondary packaging or Transport carton: The dispenser boxes are packed into transport carton. Transport carton boxes are strong enough and provide safety of devices during transportation and storage.

Therefore, a description or complete list of the various configurations/variants of the device that are intended to be made available on the market is shown as table below.

Table 4: Complete List of the Various Configurations/Variants of the Device

NO.	Topic	Description
1	Glove sizes	Available sizes Extra Small (XS) Small (S) Medium (M) Large (L) Extra Large (XL) Dimension: hand-width XS: ≤ 80 mm S: 80 ± 10 mm M: 95 ± 10 mm L: 110 ± 10 mm XL: ≥ 110 mm Dimension: length Median 240 mm for all sizes Dimension: double wall thickness Finger: Min 0.16 mm Palm: Min 0.16 mm
2	Glove packing sizes	The quantity of packing/packages shall follow the agreed specification for each brand, according to SCT.QA.FO.15.011 Approbation – Approval Packaging & Labels that could be variant quantity as the following samples; ➢ Gloves are packed 100 pcs into each dispenser box, then 10 dispenser boxes are packed into each transport carton

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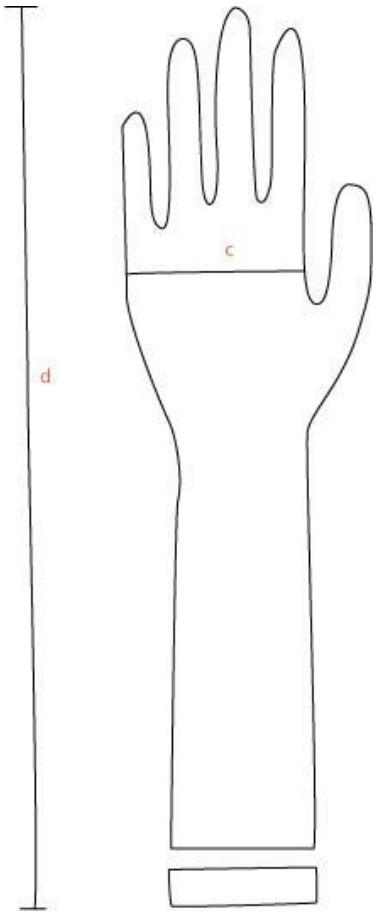
NO.	Topic	Description
3	Packaging sizes	Pack 100 pcs per each dispenser box, then pack 10 dispenser boxes per each transport carton, the dimension is as follows: Dispenser Box Packaging code: PKGPF02 Width: 122 mm Length: 240 mm Height: 65 mm Weight: 58 g Transport Carton Packaging code: PKGPF02 Width: 249 mm Length: 340 mm Height: 250 mm Weight: 271 g
4	Packaging materials	Dispensor box: Duplex Paper Transport carton: Brown Craft Paper (B-Flute)

(j) A general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams

Table 5: General Description of the Key Functional Elements

NO.	Topic	Description
1	General description of the key functional elements	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are made of natural latex and chemicals. To compensate for the lack of powder, the powder free examination gloves are either subjected to online or offline chlorination. In general, online chlorination is a finishing method for powder free gloves. The gloves are washed in a chlorine solution. The solution reduces the surface tackiness of the gloves and also gives it a softer texture allowing for gloves to be easily donned without powder. When used on latex, the chlorination process also reduces the amount of latex proteins, to make them less likely to cause an allergy.
2	Photographs	 Figure 2: Photograps of LO01 product

NO.	Topic	Description
3	Drawing	 Figure 3: Designation of length (d) and width (c) of gloves

The list of materials/compositions used for the manufacturing of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) is shown in table below:

Table 6: Material Used During Manufacturing of the Product

No.	Material/Component	Function	CAS Number
1	Natural Rubber Latex	Main Raw Material	N/A
2	Sulphur	Vulcanizing Agent	7704-34-9
3	Dithiocarbamate	Accelerator	14324-55-1, 136-23-2
4	Polymeric Sterically Hindered Phenol	Antioxidant	68610-51-5
5	Zinc Oxide	Activator	1314-13-2
6	Titanium Dioxide	Pigment	13463-67-7
7	Potassium Hydroxide	Stabilizer	1310-58-3
8	Calcium Carbonate	Additive	1317-65-3

(k) A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids

Refer to Table 6: Material Used During Manufacturing of the Product.

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(l) Technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications

Table 7: Technical Specifications (Quality Characteristics)

Description	Specification	Test-Method
BARRIER PROPERTIES Freedom from holes	 AQL ≤ 1.5	 EN 455-1
BIOCOMPATIBILITY Powder residue on powder free gloves Total Proteins	 ≤ 2.0 mg/glove ≤ 50 µg/g	 EN ISO 21171 Monitoring follows EN 455-3
PHYSICAL PROPERTIES Force at break (during shelf life) Tensile strength before/ after aging Ultimate elongation before/ after aging	EN 455-2 Median 6.0 N Min 18 MPa / 14 MPa Min 650% / 500%	 EN 455-2 ASTM D 412/ ASTM D 573 ASTM D 412/ ASTM D 573
DIMENSION Hand-width size related	EN 455-2 Size related table issued on request XS: ≤ 80 mm S: 80 ± 10 mm M: 95 ± 10 mm L: 110 ± 10 mm XL: ≥ 110 mm	EN 455-2
Total length	EN 455-2 Median 240 mm for all sizes	EN 455-2

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Description	Specification	Test-Method
Double Wall Thickness (not specify spec in EN 455-2) Finger Palm	ASTM D 3578 Min 0.16 mm Min 0.16 mm	ASTM D 3767

Performance Requirements for Quality Characteristics

- The sampling plan for in-process and final inspection follows in accordance with ISO 2859-1 "Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection;
- The Acceptance Quality Level shall conform to the AQL mentioned in agreed specification document "Technical Product Description"
- The product meets the provision of MDR (EU) 2017/745 Class I and the latest revision of EN 455 all parts.

Brochures and Catalogues

Refer to the below link:

https://www.sritranggloves.com/storage/download/factsheet/20190913-stgt-factsheet-en.pdf

Website:

Refer to the below link:

www.sritranggloves.com

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1.2. Reference to previous and similar generations of the device

(a) An overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist

Table 8: Overview of Generations of the Device Produced by the Manufacturer

Generation	Description of Generations	Product
1	Latex Examination Gloves, Powder Free, Offline Chlorination with Turning Process, Non-Sterile ➢ Inner treatment: offline chlorination ➢ Outer treatment: no treatment	Latex Examination Gloves, Powder Free *(does not exist anymore)*
2	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile ➢ Inner treatment: polymer coating ➢ Outer treatment: offline chlorination	Latex Examination Gloves, Powder Free
3	Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile ➢ Inner treatment: online chlorination ➢ Outer treatment: no treatment	Latex Examination Gloves, Powder Free

(b) An overview of identified similar devices available on the Union or international markets, where such devices exist

Table 9: Overview of Identified Similar Devices

No.	Similar Device	Product
1	Latex Examination Gloves, Powder Free, Polymer Coated, Non-Sterile ➢ Inner treatment: polymer coating ➢ Outer treatment: offline chlorination	Latex Examination Gloves, Powder Free

2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

(a) The label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold

The package labeling and marking of symbols will be shown on both packagings of product as follows;

- Dispenser box: this is a primary packaging that the gloves will be packed into a dispenser box;
- Transport carton: this is a secondary packaging that the dispenser boxes above will be packed into a transport carton

The package labeling and marking of symbols shall comply with the agreed specification of packaging for each brand according to SCT.QA.FO.15.011 Approbation – Approval Packaging & Labels as well as in accordance with the applicable regulations/ standards such as

- EN 1041 Information supplied by the manufacturer of medical devices;
- EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied;
- EN 455-3 Requirements and testing for biological evaluation (item – labelling)

(Reference: procedure refers to SCT.QA.QP.15.004 Packaging and Labeling Control)

(b) The instructions for use in the languages accepted in the Member States where the device is envisaged to be sold

The requirement for the instruction for use is not applicable for class I devices as the device can be used safely without any such instructions, however the recommended instruction for use could be determined as below.

Instruction for Use

1. Always wash hands before putting on gloves and each time you change to a new pair.
2. Take the gloves out from their original box.
3. Select glove appropriate for the task and in your size. Inform yourself prior to the application.
4. Touch only a restricted surface of the glove corresponding to wrist (at the top edge of the cuff).
5. Don the first glove by inserting your hand into the opening and pulling it over by applying a soft pull by the second hand.
6. Take the second glove with bare hand and touch only a restricted surface of the glove corresponding to wrist.
7. To avoid touching the skin of the forearm with the gloved hand, turn the external surface of the glove to be donned on the folded fingers of the gloved hand so there is a good hold on it. Thus, permitting to glove the second hand by pulling softly with the first gloved hand.
8. Once gloved, hands should not touch anything else that is not defined by indications and conditions for glove use.
9. Change gloves before beginning a different task to avoid cross contamination.
10. Pinch one glove at the wrist level to remove it, without touching the skin of the forearm, and peel away from the hand, thus allowing the glove to turn inside out.
11. Hold the removed glove in the gloved hand and slide the fingers of the ungloved hand inside between the glove and the wrist of the gloved hand. Remove the second glove by rolling it down the hand and fold the first glove into the outside palm area of the second glove. If done correctly, the user holds a pack of the outer glove turned inside and out and the contaminated surface of both gloves is within the package.
12. Discharge the removed gloves and wash hands thoroughly according the respective hygiene standards.
13. Not intended to be used as a chemical barrier.

The shelf life is normally advised to be three full years. Check the original dispenser instructions for details.

3. DESIGN AND MANUFACTURING INFORMATION

(a) Information to allow the design stages applied to the device to be understood

The design stages will be followed the steps below:

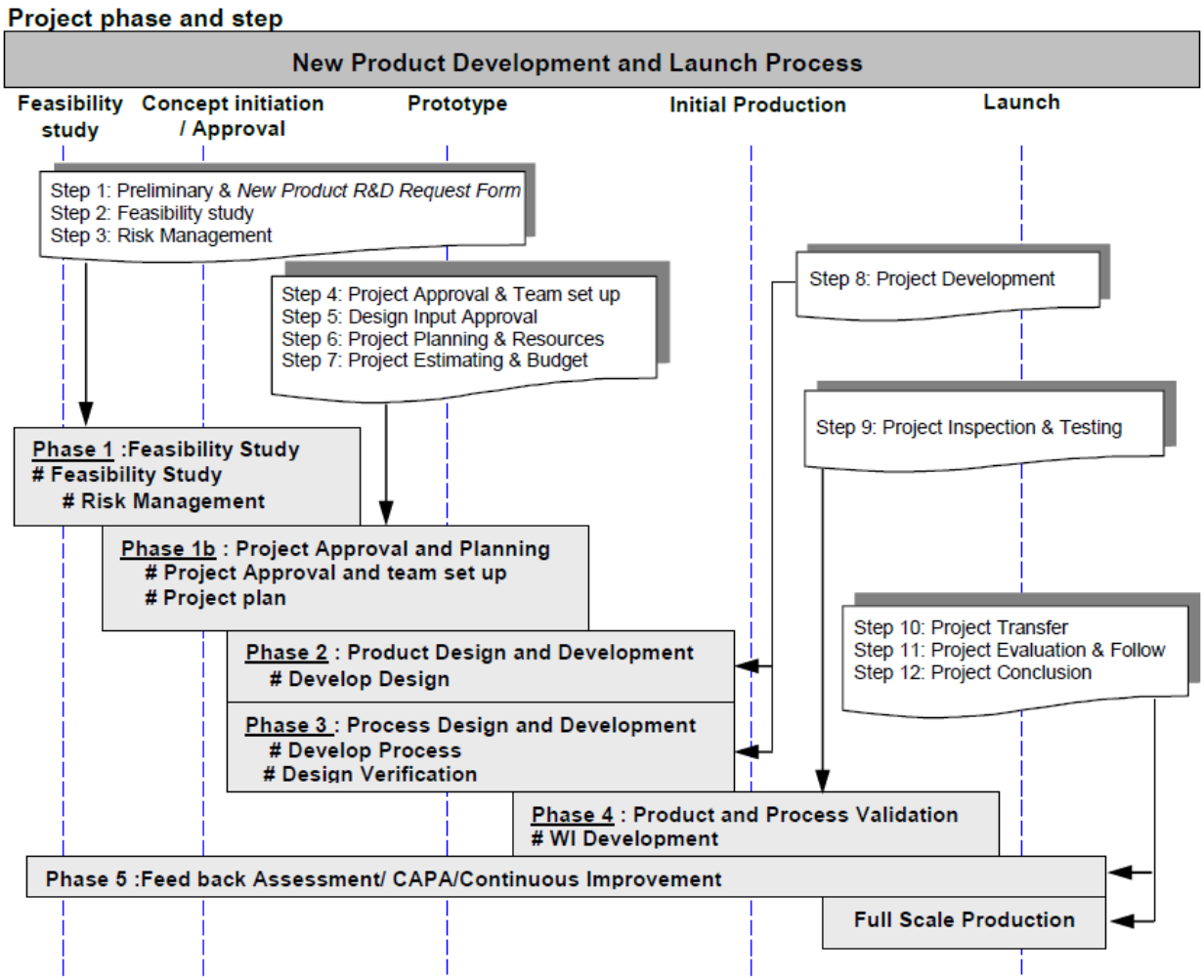

Figure 4: Design stages

(Reference: procedure refers to SCT.QA.QP.04.001 Design Control)

(b) Complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring, and the final product testing. Data shall be fully included in the technical documentation

Table 10: Complete Information and Specifications

Description	Specification	Test-Method
BARRIER PROPERTIES Freedom from holes	 AQL ≤ 1.5	 EN 455-1
BIOCOMPATIBILITY Powder residue on powder free gloves Total Proteins	 ≤ 2.0 mg/glove ≤ 50 µg/g	 EN ISO 21171 Monitoring follows EN 455-3
PHYSICAL PROPERTIES Force at break (during shelf life) Tensile strength before/ after aging Ultimate elongation before/ after aging	EN 455-2 Median 6.0 N Min 18 MPa / 14 MPa Min 650% / 500%	 EN 455-2 ASTM D 412/ ASTM D 573 ASTM D 412/ ASTM D 573
DIMENSION Hand-width size related	EN 455-2 Size related table issued on request XS: ≤ 80 mm S: 80 ± 10 mm M: 95 ± 10 mm L: 110 ± 10 mm XL: ≥ 110 mm	EN 455-2
Total length	EN 455-2 Median 240 mm for all sizes	EN 455-2

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Description	Specification	Test-Method
Double Wall Thickness (not specify spec in EN 455-2) Finger Palm	ASTM D 3578 Min 0.16 mm Min 0.16 mm	ASTM D 3767

Performance Requirements for Quality Characteristics

- The sampling plan for in-process and final inspection follows in accordance with ISO 2859-1 "Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection;
- The Acceptance Quality Level shall conform to the AQL mentioned in agreed specification document "Technical Product Description"
- The product meets the provision of MDR (EU) 2017/745 Class I and the latest revision of EN 455 all parts.

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Manufacturing Process

The manufacturing process for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) is shown as below:

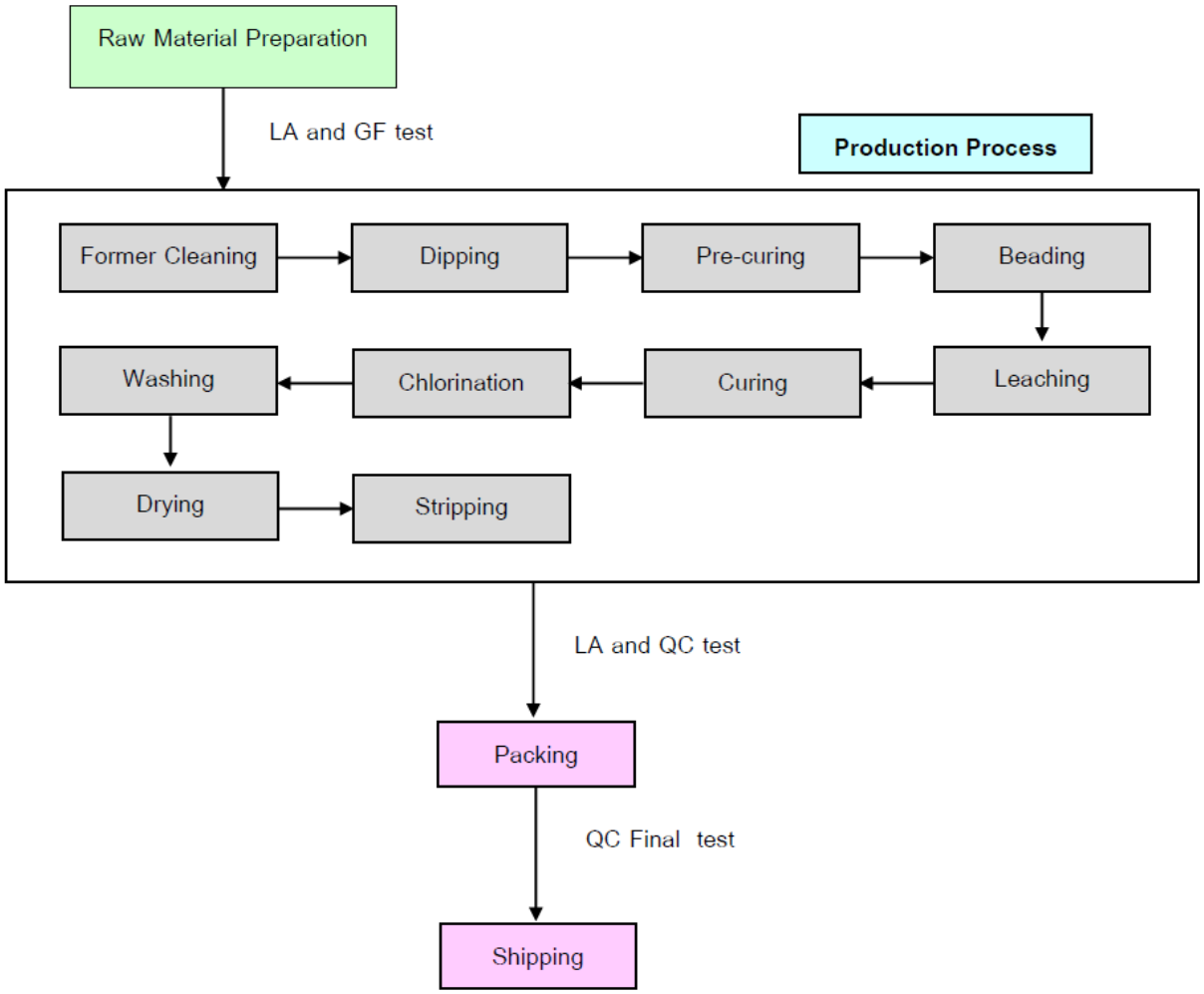

Figure 5: Manufacturing process of LO01

(Reference: procedure refers to SCT.QA.QP.09.001 Production Control)

Validation

The validation for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) consists of validation plan and validation report which shown as follows:

Validation Plan

(Performance Qualification Protocol of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade, LO01)

Reference: VA.QP.PQ.01.053/a250919

1. Purpose

To establish confidence through appropriate testing that the finished product produced by process of group line Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are effective and meet all release requirements for functionality and safety.

2. Scope

This Performance Qualification Protocol is applicable for group line of production process of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01).

3. Process Description and Principle of Operation

According to manufacturing process flow chart, work instruction of production process for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01).

4. Requirements for the Process

According to parameter specifications of production process for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01).

5. Inspection/ Test Method for Measuring the Evaluation Results

According to In-Process and Final Inspection Sampling Plan.

6. Manufacturing Materials, Equipment and Calibration

To ensure the approval of materials, availability of equipment and calibration status.

7. Acceptance Criteria

The performance qualification for group line of production process of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) will be acceptable if fulfilment of following criteria;

- All process parameters meet specification defined.
- All properties of product meet on requirements.

8. Conclusion

To summarize the conclusion of validation for Performance Qualification of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01).

9. Established by

Mr. Burin Meethip, Assistant Technical Assurance Manager

10. Reviewed and Approved by

Ms. Nawarat Arunpan, Assessment and Technical Assurance Manager

Validation Report

(Performance Qualification Report of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade, LO01)

Reference: VA.RE.PQ.01.074/a091019

1. Purpose

To establish confidence through appropriate testing that the finished product produced by process of group line Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) are effective and meet all release requirements for functionality and safety.

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5. Inspection/ Test Method for Measuring the Evaluation Results

According to In-Process and Final Inspection Sampling Plan.

6. Manufacturing Materials, Equipment and Calibration

The approval of materials, availability of equipment and calibration status, are completed prior validation.

7. Acceptance Criteria

The performance qualification for group line of production process of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) will be acceptable if fulfilment of following criteria;

- All process parameters meet specification defined.
- All properties of product meet on requirements.

8. Conclusion

The performance qualification for group line of production process of Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) is completed, acceptable and complied to the following criteria;

- All process parameters meet specifications defined.
- All properties of product meet on requirements.

9. Established by

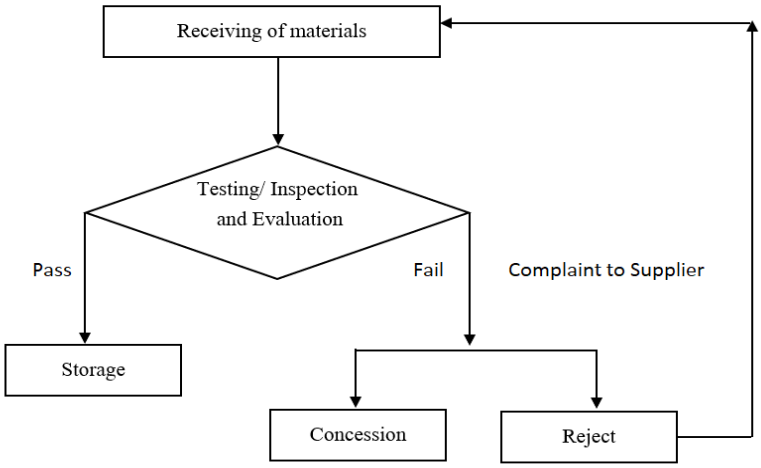
Mr. Burin Meethip, Assistant Technical Assurance Manager

10. Reviewed and Approved by

Ms. Nawarat Arunpan, Assessment and Technical Assurance Manager

Quality Assurance Monitoring and the Final Product Testing

Table 11: Quality Assurance Monitoring and the Final Product Testing

No.	Quality Assurance Inspection and Testing	Description
1	Incoming materials inspection	This step is to inspect and ensure that the quality of materials include latex, chemicals, packaging and glove molds meet the specifications defined of each material.  Figure 6: Flow chart of incoming materials inspection

No.	Quality Assurance Inspection and Testing	Description
2	Ingredient and compounding preparation inspection	This step is to inspect and ensure that the quality of ingredients and compounds after preparation meet the specifications defined before approval to use in production line.

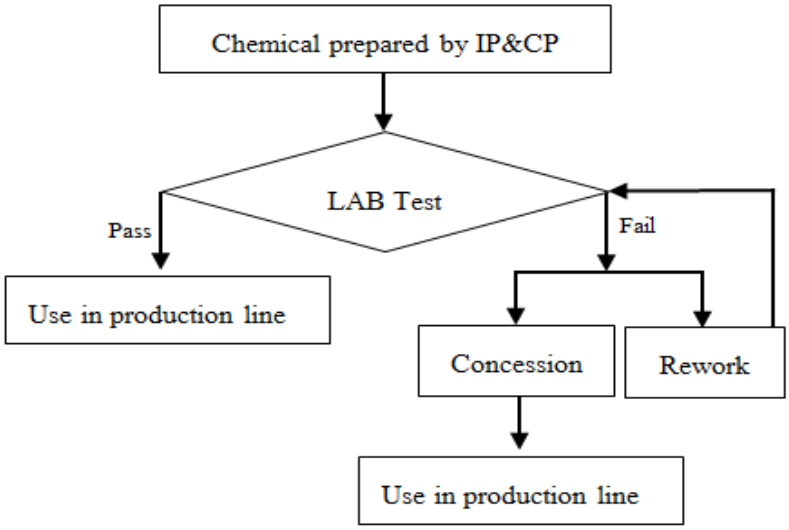
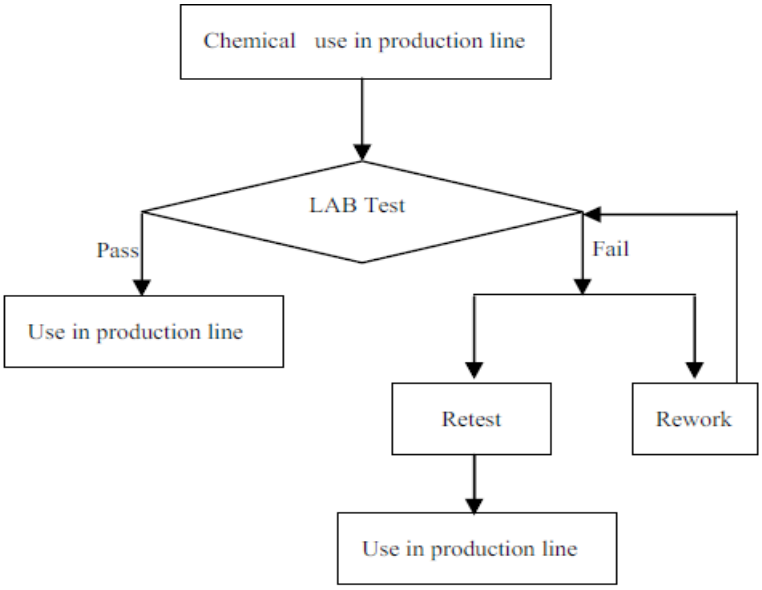


Figure 7: Flow chart of ingredient and compounding preparation inspection

No.	Quality Assurance Inspection and Testing	Description
3	Production line/ chemical in line inspection	This step is to check and ensure that parameters control in production line meet the specifications defined as well as to inspect and ensure that the chemicals in production line meet the specifications defined.  Figure 8: Flow chart of chemical in line inspection

No.	Quality Assurance Inspection and Testing	Description
4	In-process & Final inspection	This step is to inspect and ensure that the quality of gloves/ packaging meet the specifications defined.

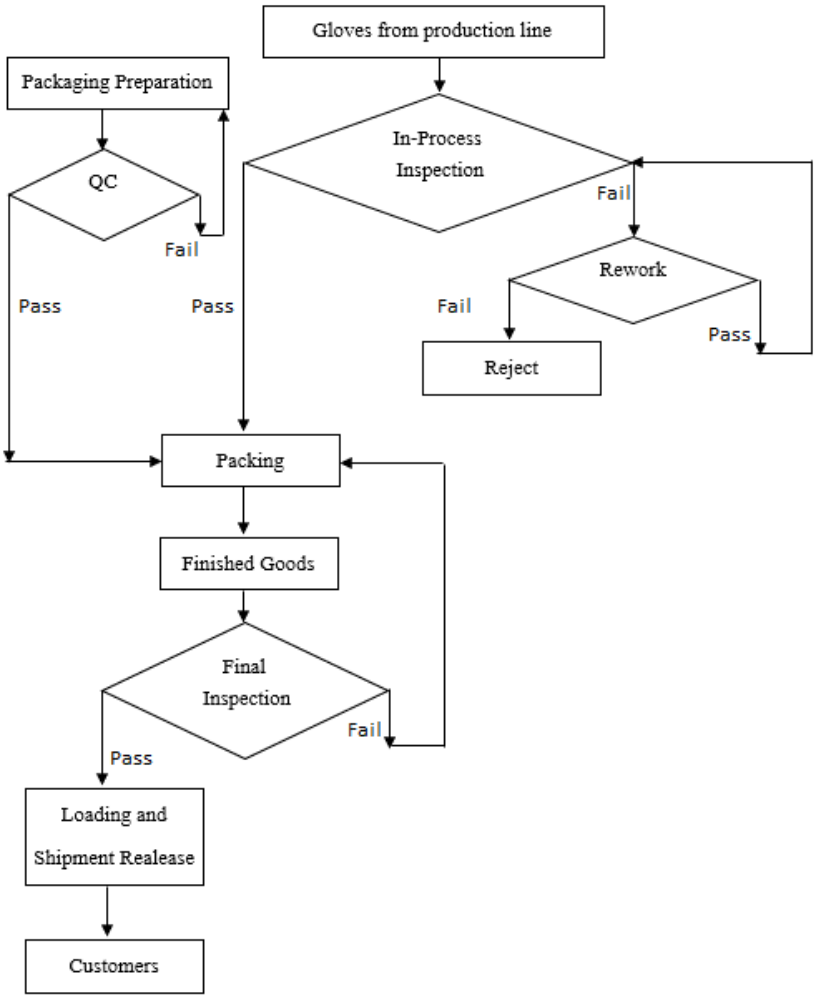


Figure 9: Flow chart of in-process & final inspection

(c) Identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed

Manufacturing Site Facilities

Sri Trang Gloves (Thailand) Public Company Limited

Site 1 (STGT-HY1): 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
(Scope: Design and Development, Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Site 2 (STGT-HY2): 109/2 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
(Scope: Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Site 3 (STGT-HY3): 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
(Scope: Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Site 4 (STGT-HY4): 110/3 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230 Thailand
(Scope: Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Site 5 (STGT-SR): 189 Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160 Thailand
(Scope: Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Site 6 (STGT-TG): 85 Moo 6, Kuan Thani, Kantang, Trang 92110 Thailand
(Scope: Production and Distribution of Sterile and Non-Sterile Examination Gloves)

Design and development is a centralised function located at address of site 1, to support for all manufacturing site facilities of Sri Trang Gloves (Thailand) Public Company Limited.

4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

(a) The general safety and performance requirements that apply to the device and an explanation as to why others do not apply

(b) The method or methods used to demonstrate conformity with each applicable general safety and performance requirement

(c) The harmonized standards, CS or other solutions applied

(d) The precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation

(Reference: SCT.QA.FO.02.008 General Safety and Performance Requirements Checklist, Latex Powder Free Examination Gloves, Non-Sterile)

5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

(a) The benefit-risk analysis referred to in Sections 1 and 8 of Annex I

Based on the conducted risk analysis for the Latex Examination Gloves, Powder Free, Non-Sterile product, the foreseeable risks have been identified and evaluated in most cases as acceptable with respect to the intended application and use of the products. Counteractions have been taken for those items for which an initially unacceptable risk has been identified. Subsequently, the performed implementations were verified. Finally, it can be determined that no unacceptable residual risk exists with the products either individually or cumulatively, that outweighs the benefits from the use of the products.

(b) The solutions adopted and the results of the risk management referred to in Section 3 of Annex I

Based on the conducted risk analysis for the Latex Examination Gloves, Powder Free, Non-Sterile product, the foreseeable risks have been identified and evaluated in most cases as acceptable with respect to the intended application and use of the products. Counteractions have been taken for those items for which an initially unacceptable risk has been identified. Subsequently, the performed implementations were verified. Finally, it can be determined that no unacceptable residual risk exists with the products either individually or cumulatively, that outweighs the benefits from the use of the products.

(Reference: Risk Management Plan and Risk Analysis Report of Latex Powder Free Examination Gloves, Non-Sterile)

6. PRODUCT VERIFICATION AND VALIDATION

6.1. Pre-Clinical and Clinical Data

(a) Results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications

(b) Detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular

- The biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user

The biocompatibility tests for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) shown as the following table:

Table 12: Biocompatibility Tests

No.	Test Item	Reference Standard	Test Institute	Test Report	Summary Result
1	Cytotoxicity	EN ISO 10993-5	Nelson Labs	1156407-S01.1	Grade 0 at dilution 1: 8 No cell lysis, intracytoplasmic granules
2	Irritation	EN ISO 10993-10	Toxikon	19-02021-G2	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article
3	Skin Sensitization	EN ISO 10993-10	Toxikon	19-02021-G1	The test article is classified as a non-sensitizer
4	Viral Penetration	ASTM F 1671	Nelson Labs	1156409-S01.1	Pass, acceptable

- Physical, chemical and microbiological characterisation

The physical, chemical and microbiological characterization tests for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) shown as the following table:

Table 13: Physical, Chemical and Microbiological Characterization Tests

No.	Test Item	Reference Standard	Test Institute	Test Report	Summary Result
1	Freedom from holes	EN 455-1	TUV SUD PSB Pte. Ltd.	7191205854-EEC19/01-WBH	Pass
2	Dimension	EN 455-2	TUV SUD PSB Pte. Ltd.	7191205854-EEC19/02-WBH	Pass
3	Tensile	EN 455-2	TUV SUD PSB Pte. Ltd.	7191205854-EEC19/03-WBH	Pass
4	Protein	EN 455-3	Lembaga Getah	LGM/BTK/UPB/5.10/CP/1804/0169	Pass
5	Residual Powder	EN 455-3	TUV SUD PSB Pte. Ltd.	7191205854-CHM19-JS-05	Pass

- Electrical safety and electromagnetic compatibility

This requirement is not applicable, as examination gloves are not relating to electrical safety and electromagnetic compatibility.

- Software verification and validation

This requirement is not applicable, as software is not used in finished devices – examination gloves.

- Stability, including shelf life

The stability, including shelf life test for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) shown as the following table:

Table 14: Stability and Shelf Life Test

No.	Test Item	Reference Standard	Test Institute	Test Report	Summary Result
1	Stability and Shelf Life	EN 455-4	In-house testing	STGTSR-SL-19-004	Based on conducted the stability study, the real time shelf life for Latex Examination Gloves, Powder Free, Chlorinated, Non-Sterile, EU Spec, Medical Grade (LO01) is up to 5 years

- Performance and safety

Design Validation

The design of this product has been validated to ensure the performance and safety of examination gloves according to the following evaluation items:

- Fit/ comfort
- Skin irritation
- Tactile sensitivity (dry, wet)
- Grip
- Ease of donning
- Odor

- Color
- Strength/ durability

Summary: the result of design validation is acceptable.

(Reference: procedure refers to SCT.QA.QP.04.001 Design Control)

Packaging Verification

The packaging is also verified the performance and safety to ensure that the package are strong enough and and provided safety of devices during transportation and storage.

The box compression test (BCT) to the package shown as the following:

Table 15: Box Compression Test of Packaging

Product	Package	BCT Requirement (Kgf)	BCT Results (Kgf)
L001	Pack 100 glove pcs per dispenser box, 10 dispenser boxes per carton	269.9	332.8

(c) The clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV

Conclusion of Clinical Evaluation

The clinical evaluation clearly demonstrates that the Latex Examination Gloves, Powder Free, Non-Sterile are in conformity with the relevant general safety and performance requirements of MDR 2017/745 (Annex I) by compliance to the requirements of EN 455. The current information material is considered adequate with respect to the intended user.

The performance and safety of Latex Examination Gloves, Powder Free, Non-Sterile have been established and risk associated with the use of these devices are acceptable when weighed against the benefits to the patient.

Taken together, the performance and safety of the devices have been established and risks associated with the use of the devices are acceptable when weighed against the benefit for the user and patient.

(Reference: Clinical Evaluation Report, Examination Gloves, Non-Sterile)

(d) The PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable

The PMCF Plan outlines the methods and chosen frames for updating the clinical evaluation on a regular basis, incorporating new sources of information and checking on identified risks and the correct assessment of those in the risk management activities.

Examination gloves, both sterile and non-sterile, are used since centuries and the materials NBR and NR have been well established with several hundred billion gloves per year consumed all over the world. From this fact and the current post-market surveillance data available, there might be the possibility explored, that PMCF studies are not necessary to evaluate the safety, quality or performance of that particular medical devices.

(Reference: Post-Market Clinical Follow-up Plan)

6.2. Additional Information Required in Specific Cases

(a) Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality, and usefulness, taking account of the intended purpose of the device

This requirement is not applicable, as examination gloves are not classified as medicinal product devices.

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(b) Where a device is manufactured utilizing tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1 (6, and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1 (10), a statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I.

This requirement is not applicable, as examination gloves are not manufactured utilizing tissues or cells of human or animal origin, or their derivatives.

(c) In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions

This requirement is not applicable, as examination gloves are not composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body.

(d) In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of Annex I, the justification referred to in Section 10.4.2 of that Annex

This requirement is not applicable, as examination gloves do not contain of CMR or endocrine-disrupting substances.

(e) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilization, and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues

This requirement is not applicable, as this kind of examination gloves is non-sterile and do not define microbiological condition.

(f) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications

This requirement is not applicable, as examination gloves are not classified as measuring function devices.

(g) If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer

This requirement is not applicable, as examination gloves are not to be connected to other devices in order to operate as intended.

TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

1.1. The post-market surveillance plan drawn up in accordance with Article 84

Post-Market Surveillance Plan

The post-market surveillance (PMS) is the activities carried out to gain information about the quality, safety or performance of medical devices that have been placed in the market.

The post-market surveillance and action system consists of four main steps as follows:

- Step 1 Surveillance Input

The surveillance input is a channel to gain information about the quality, safety or performance of medical devices that have been placed in the market, which could be determined as the table below.

Table 16: Plan & Time Schedule

NO.	Action	Timeframe	Desired Outcome
1	Complaint analysis	Without undue delay after incoming complaint information	Proper case studies and statistics
2	Competitor analysis	At least once a year	Comparison & studying of advancement of state of the art
3	Literature review	At least all two years	Proper literature section in the clinical evaluation report
4	Interviews with users, customers, conferences, regulators and notified bodies	During trade shows, fairs, customer visits and inspections	Advanced understanding of changed settings, applications, experiences, complaints, technologies and regulations
5	Review of authority reports & actions taken by regulators	Without undue delay after receiving an authority reports or learning about an action taken by a regulatory	Learnings from case studies

NO.	Action	Timeframe	Desired Outcome
6	Review of public incident reporting databases	Once a year	Learnings from case studies
7	Preclinical Data & Testing	Per Demand	Preclinical assessments shall help to study product performances under standardized and objective settings.
8	Proactive questionnaires	Once a quarter (starting with Q3 2020)	Raising the level of understanding and awareness on customer side & getting feedback on more complex and rare product deficiencies

- Step 2 Investigation & Analysis

After receiving the post-market surveillance information above, the person in charge and all involved in each PMS topic above shall perform investigate and analysis those information as well as to find and summarize the investigation and analysis output for further action and communication.

- Step 3 Action

The action shall be taken following the output from investigation and analysis in order to monitor and maintain the quality, safety or performance of medical devices. Include the action shall comply with the applicable standards, regulations and laws in each market.

Example of action; response of complaint investigation, adverse event reporting, advisory notice issuing, recall/ correction and removal, corrective action and prevention action; process, design, labeling, training, and so on.

- Step 4 Communication

Together with action shall be considered for communication also. The communication shall comply with the applicable standards, regulations and laws in each market.

Example of communication; to communicate to Stakeholders, Regulatory Authorities, Representative, Notified Body, Customers, Distributors, Suppliers and so on.

The overall meeting for post-market surveillance (PMS) will be performed at least once a year to summarize the overall feedback through the year in order to ensure the products are still under safety, quality and performance of medical devices.

(Reference: procedure refers to SCT.QA.QP.19.001 Feedback, Post-Market Clinical Follow-up Plan)

1.2. The PSUR referred to in Article 86 and the post-market surveillance report referred to in Alticle 85

Regarding the post-market surveillance, Sri Trang Gloves (Thailand) Public Company Limited has appropriate procedures in place to handle feedback from the market, the last overall meeting for post-market surveillance (PMS) could be determined the output from a meeting as follows.

Table 17: Post-Market Surveillance Report

NO.	Action	Timeframe	Report
1	Complaint analysis	Without undue delay after incoming complaint information	Proper case studies and statistics *"The determined complaint rates reside in a general accepted level, there is no critical compaints concerning alleged deficiencies related to safety or performance that require to recall or withdrawal the products from the market, there is no competent authority post market surveillance inquiries"*
2	Competitor analysis	At least once a year	Comparison & studying of advancement of state of the art *"The determined competitor analysis shows the comparison and studying of competitors for improvement process"*
3	Literature review	At least all two years	Proper literature section in the clinical evaluation report *"The determined literature reviews show the studying of literature for improvement process and proper literature section in the clinical evaluation report"*

NO.	Action	Timeframe	Report
4	Interviews with users, customers, conferences, regulators and notified bodies	During trade shows, fairs, customer visits and inspections	Advanced understanding of changed settings, applications, experiences, complaints, technologies and regulations *"The determined interviews with users, customers, conferences, regulators and notified bodies show advanced understanding of changed settings, applications, experiences, complaints, technologies and regulations"*
5	Review of authority reports & actions taken by regulators	Without undue delay after receiving an authority reports or learning about an action taken by a regulatory	Learnings from case studies *"The determined review of authority reports & actions taken by regulators show thr learnings from case studies for improvement process"*
6	Review of public incident reporting databases	Once a year	Learnings from case studies *"The determined review of public incident reporting databases shows thr learnings from case studies for improvement process"*
7	Preclinical Data & Testing	Per Demand	Preclinical assessments shall help to study product performances under standardized and objective settings. *"The determined preclinical data & testing shows all product performances meet the standardized and objective settings"*
8	Proactive questionnaires	Once a quarter (starting with Q3 2020)	Raising the level of understanding and awareness on customer side & getting feedback on more complex and rare product deficiencies *"Based on the feedback on the proactive questionnaire regarding the irritation of gloves, all feedback received confims that there is no the case of irritation"*

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Therefore, from a meeting, it could be determined that the products are still under safety, quality and performance of medical devices.

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REFERENCES

Table 18: List of Applicable Regulations and Standards

No.	Regulation/ Standard Number	Regulation/ Standard Name
1	MDR (EU) 2017/745	Medical Device Regulation
2	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3	ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4	ISO 9001: 2015	Quality management systems – requirements
5	ISO 14971: 2019	Medical devices - application of risk management to medical devices
6	EN 455-1: 2020	Requirements and testing for freedom from holes
7	EN 455-2: 2015	Requirements and testing for physical properties
8	EN 455-3: 2015	Requirements and testing for biological evaluation
9	EN 455-4: 2009	Requirements and testing for shelf life determination
10	ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
11	ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
12	ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization
13	ASTM F1671: 2013	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system
14	ASTM D3578: 2019	Standard specification for rubber examination gloves
15	EN 1041: 2008+A1: 2013	Information supplied by the manufacturer of medical devices
16	EN ISO 15223-1: 2016	EN ISO 15223-1 Symbols to be used with medical device labels, labelling and information to be supplied
17	ASTM D7160: 2016	Determination of expiration dating for medical gloves

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No.	Regulation/ Standard Number	Regulation/ Standard Name
18	ASTM D7161: 2016	Determination of real time expiration dating of mature medical gloves stored under typical warehouse conditions
19	EN 420: 2003+A1: 2009	Protective gloves - General requirements and test methods
20	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
21	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
22	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
23	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
24	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

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