CONFIDENTIAL

Technical file

IN ACCORDANCE WITH ANNEX III OF PPE REGULATION (EU) 2016/425

Covering PPE models

Product

Latex Powder Free Online Chlorination Gloves,

Non Sterile

DOCUMENT NO : TF-PE-LF-01-305	**EFFECTIVE DATE :** 01 April 2019
REVISION : A	

CONTENTS

SECTION 1 COMPANY INFORMATION

1.1 COMPANY STRUCTURE

Sri Trang Gloves (Thailand) Public Company Limited (STGT) was established on 9 January, 1989 and subsidiary company of Sri Trang Agro-Industry Public Company Limited (STA).

COMPANY STRUCTURE

Sri Trang Gloves (Thailand) Public Company Limited has 1 head office and 3 main branches facilities in Hat Yai , Suratthani and Trang as the following addresses.

Head Office

Sri Trang Gloves (Thailand) Public Company Limited

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

Manufacturing Plant Name

Sri Trang Gloves (Thailand) Public Company Limited

110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, Thailand

109/2 Kanjanavanit road, Pahtong, Hat Yai, Songkhla 90230, Thailand

352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, Thailand

189 Moo 7,Phlai Wat, Kanchanadit, Surat Thani 84160, Thailand

85 Moo 6, KhuanThani, Kantang, Trang 92110, Thailand

SECTION 2 PRODUCTION DETAILS

2.1 Product Description

Latex Powder Free Offline Chlorination Gloves, Non Sterile

a) The gloves are manufactured by

Sri Trang Gloves (Thailand) Public Company Limited

Consisted of 5 facilities, 3 branches (Hat Yai, Suratthani and Trang)

Plant 1 Address: 110 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla 90230, Thailand

Plant 2 Address: 109/2 Kanjanavanit road, Pahtong, Hat Yai, Songkhla 90230, Thailand

Plant 3 Address: 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230, Thailand

Plant 4 Address: 189 Moo 7, Phlai Wat, Kanchanadit, Surat Thani 84160, Thailand

Plant 5 Address: 85 Moo 6, KhuanThani, Kantang, Trang 92110, Thailand

b) Type of Gloves: Latex Powder Free Online Chlorination Gloves, Non Sterile

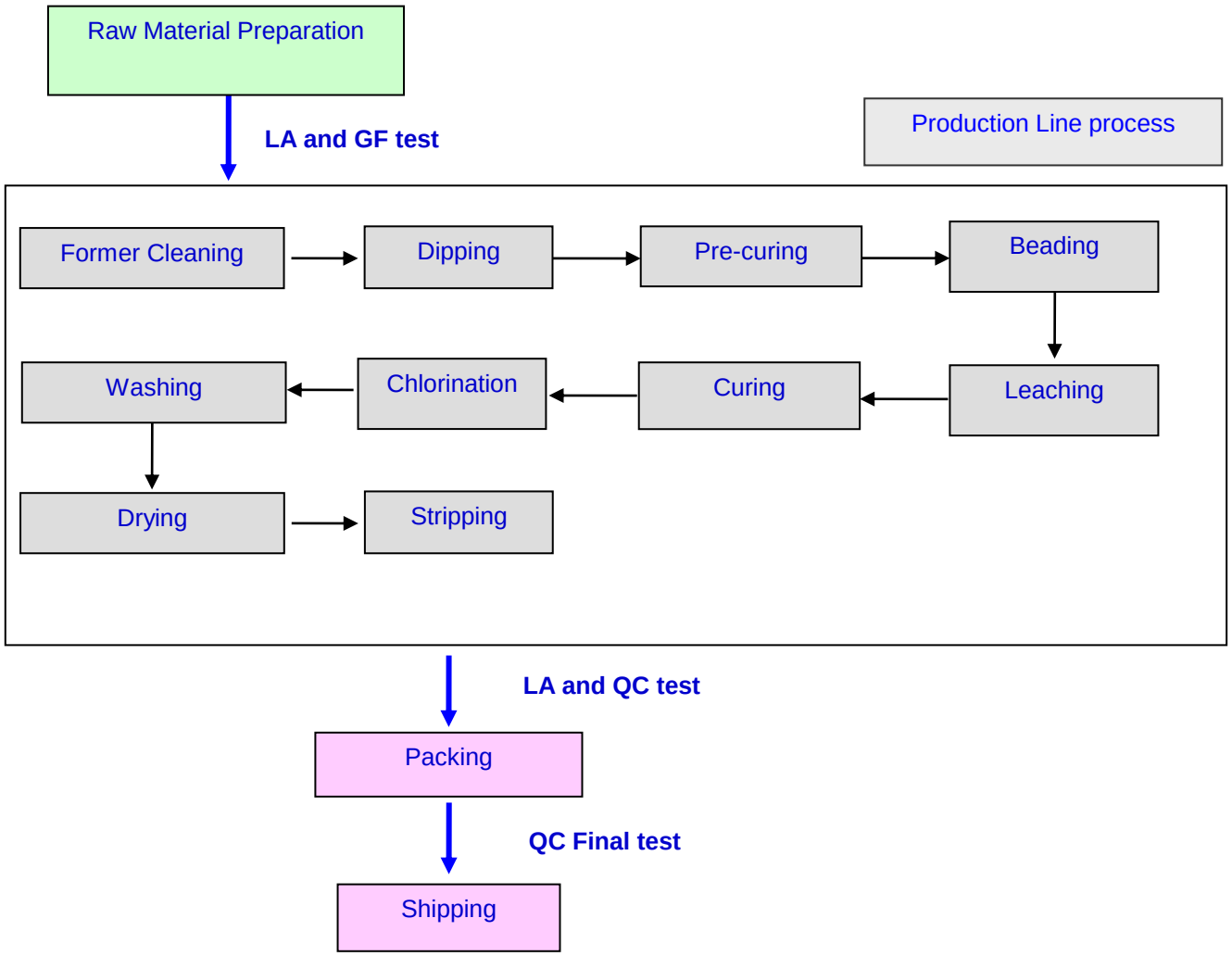
c) Item No. TF-PE-LF-01-305

Item No.	Product Code	Product Description	Manufactured Sites
TF-PE-LF-01-305	LO01	Latex Powder Free Online Chlorination Gloves, Non Sterile	1 site at Hat Yai branch (address 352 Kanjanavanit Road, Pahtong, Hat Yai, Songkhla, 90230, Thailand) And Suratthani branch

2.2 Brands

Brands	Product Sold
1.Sritrang Latex Powder Free Gloves, Non Sterile	LO01

2.3 Flow chart of manufacturing process: Latex Powder Free Online Chlorination Gloves, Non Sterile



The production process the company has proceed to produce the gloves according to QA.QP.GE.09.001_Production Control

SECTION 3 RISK ASSESSMENT

Risk assessment is to define requirements for estimating and controlling the risks related to gloves by identifying hazards related to the device, evaluating the risks associated with the hazards, and controlling the risks through mitigating actions and the continuous monitoring of the effectiveness of the controls.

Risk Management Process

The risk management process included the following elements:

- Risk Analysis
- Risk Evaluation
- Risk Control

Overview of the risk management process described in page10th begin during the design input phase of a new device and will continue through its use. The risk management process will analyze, evaluate and control the risks associated with the device's design, manufacturing processes, use activities.

3.1 Risk Analysis

3.1.1 Device Intended Use Requirements

The intended use requirements for each type of device shall be defined during the design input phase, and will include the following, as a minimum:

3.1.1 The performance, biological and chemical requirements related to the safe and effective use of the device.

3.1.2 The environmental conditions under which the device is transported, stored and used.

3.1.3 User interface (human factors) requirements Question that can be used to identify medical device characteristics that could impact on safety for Guideline to identify Intended Use.

3.1.2 Hazard Identification

3.2.1 Design Based on the device's intended use requirements, a list of hazard(s) that might affect the safe and effective use the device and any reason able for eseeable misuse conditions shall be established.

3.2.2 Manufacturing Processes Hazard(s) associated with each manufacturing process step, including operator error, which might affect the safe and effective use of the device shall be identified and documented. All possible causes for a specific hazard shall be determined, and identified to the specific hazard.

Both process must concern in normal condition and in fault condition of device.

Normal Condition: The meaning of Normal condition, It means that the normal characteristics of the device and ready to use. And we cannot see or know for the abnormal characteristics by visual.

In fault condition: The meaning of in fault condition, It means that the abnormal characteristics of the device and risk when the patient or user use the device. Such as pin hole of glove

3.1.3 Risk Estimation

A degree of risk is determined for each cause of a specific hazard. The degree of risk is calculated based on the probability of occurrence, level of severity, according to the acceptance matrix criteria as below

Sources of information in determining the level of risk are, but not limited to:

- Published standards
- Technical and scientific literature
- Complaint history and filed actions
- Clinical evaluations
- CAPA system
- Nonconformance data

3.2 Risk Evaluation

The level(s) of acceptable risk shall be predetermined for each type of device. The acceptance criteria described as below and documented in the Risk Management File.

Acceptance matrix before and after mitigations

Severity / Probability	Customer Dissatisfaction (1)	Temporary Impairment (2)	Permanent Impairment (3)	Possible Death (4)
Frequent (6)	6	12	18	24
Probable (5)	5	10	15	20
Occasional (4)	4	8	12	16
Rare (3)	3	6	9	12
Improbable (2)	2	4	6	8
Incredible (1)	1	2	3	4

Acceptable	Negligible risk
Tolerable (AFAP)	Tolerable risk but should be reduced to a level (As Far As Possible)
Intolerable	Cannot accept

Severity: Identified in 4 Level as following;

	Ranking	Definition
Customer Dissatisfaction	1	No Infection/ Contamination. The customer dissatisfaction. Such as found incompletely bead, Sticky etc.
Temporary Impairment	2	Infection/Contamination / Allergy /Temporary impairment such as substances through the skin, abrasion
Permanent Impairment	3	Infection/Contamination / Allergy/Long term impairment such as severe cuts or lacerations, chemical burn
Possible Death	4	Death

Probability: Identified in 6 Level as following;

	Ranking	Ratio complaint topic per 1,000,000 Pcs
Incredible	1	<1.000
Improbable	2	<2.000 to 10.000
Rare	3	<11.000 to 100.000
Occasional	4	<101.000 to 1,000.000
Probable	5	<1,001.000 to 10,000.000
Frequent	6	> 10,000.000

3.3 Risk Control

When risk reduction required, risk control activities, shall be performed.

3.3.1 Risk control option analysis

Identify risk control measure(s) that are appropriate for reducing the risk(s) to an acceptable level; use one of the following in the priority order listed.

- Inherent safety by design
- Protective measures in the medical device itself or in the manufacturing process
- Information for safety.

3.4 Risk Assessment

What are the hazards?	What type of injury may occur?	Rate severity of hazard / injury? (1 to 4)	What is the likelihood of the hazard or injury occurring? (1 to 6)	Severity x likelihood rating	What design considerations are applied to mitigate the risk of injury	Which standard is being applied to assess the level of protection afforded?
Tearing easily	Temporary Impairment, substances through the skin	2	1	2	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3. Laboratory sampling gloves from in process to check the quality according to standard. 4. Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard.	EN 455-1 EN 455-2 EN 374-2 EN 374-4
Hole	Temporary Impairment, substances through the skin	2	1	2	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3. Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard.	EN 455-1 EN 374-2
Not endure alcohol	Temporary Impairment, substances through the skin	2	1	2	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3. Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard.	EN 455-1 EN 374-2 EN 374-4 EN 16523-1

Crack	Temporary Impairment, substances through the skin	2	1	2	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3. Laboratory sampling gloves from in process to check the quality according to standard. 4. Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard.	EN 455-1 EN 374-2 EN 374-4 LA.TM.GE.10.038
Force	The customer dissatisfaction.	1	1	1	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2. Laboratory sampling gloves from in process to check the quality according to standard. 3.Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard	EN 455-2
Thin glove	The customer dissatisfaction.	1	1	1	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3. Laboratory sampling gloves from in process and before release to check the quality according to standard. 4.Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard	EN 455-1 EN 455-2 EN 374-2 EN 374-4 EN 16523-1 ASTM 3578
Thickness	The customer dissatisfaction.	1	1	1	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2. Laboratory sampling gloves from in process and before release to check the quality according to standard.	ASTM 3578

Permeability	Temporary Impairment, substances through the skin	2	1	2	1. Control and Monitoring the production process every shift according to PR.SO.DL.09.009_Production Control. 2.QC inspection gloves of each lot to check the Quality according to EN455-1 3.Cross check the quality of gloves by sending to test from External Laboratory according to PPE standard	EN 455-1 EN 374-2 EN 347-4 EN 16523-1

SECTION 4 GROUP AND PRODUCT DESCRIPTIONS

Group Number	Latex Powder Free Gloves, Non Sterile TF-PE-LF-01-305 (LO01)
Product Standard	EN 420:2003+A1:2009 EN ISO 374-1:2016 EN 374-2:2014 EN 374-4:2013 EN ISO 374-5:2016 EN 16523-1:2015
Product code / name	**Product Description**
Latex Powder Free Online Chlorination Gloves, Non Sterile (LO01)	Latex Powder Free Gloves, Non Sterile Inner coating, Extra rough (Textured) at finger tip surface.

4.1 PRODUCT DESCRIPTION

4.1.1 PRODUCT

Product Name: Latex Powder Free online chlorination Gloves, Non Sterile

Product Code: LO01

INTENDED USE

Industrial activities, Latex glove that gives protection against low risk solvents & other reagents and has good dexterity. This glove protection from potential chemical spills and drips. Not recommended for mechanical risks.

MATERIAL

Natural rubber latex

Warning: This product contains natural rubber latex which may cause allergic reactions.

SURFACE TREATMENT

No donning powder is used.

Halogenation and extensive washing in water online.

SHAPE

Straight fingers, thumb and fingers in one plane, fits either hand (ambidextrous)

Rolled rim

SIZES

Extra small (XS), Small (S), Medium (M), Large (L), Extra large (XL)

COLOR

Pale yellow

4.2 Size Chart/Diagram (millimeters)

Table 1: The Size Chart/Diagram (millimeters) for product LO01

Items	Specification Ref: EN 455-2
1.Length (mm.)	
- XS	Median 240
- S	Median 240
- M	Median 240
- L	Median 240
- XL	Median 240
2. Width (mm.)	
- XS	</= 80
- S	80+/-10
- M	95+/-10
- L	110+/-10
- XL	>/=110
3.Single Wall Thickness (mm)	ASTM D3578
- Finger	Min 0.08
- Palm	Min 0.08

4.3 Size Chart/Diagram (millimeters)

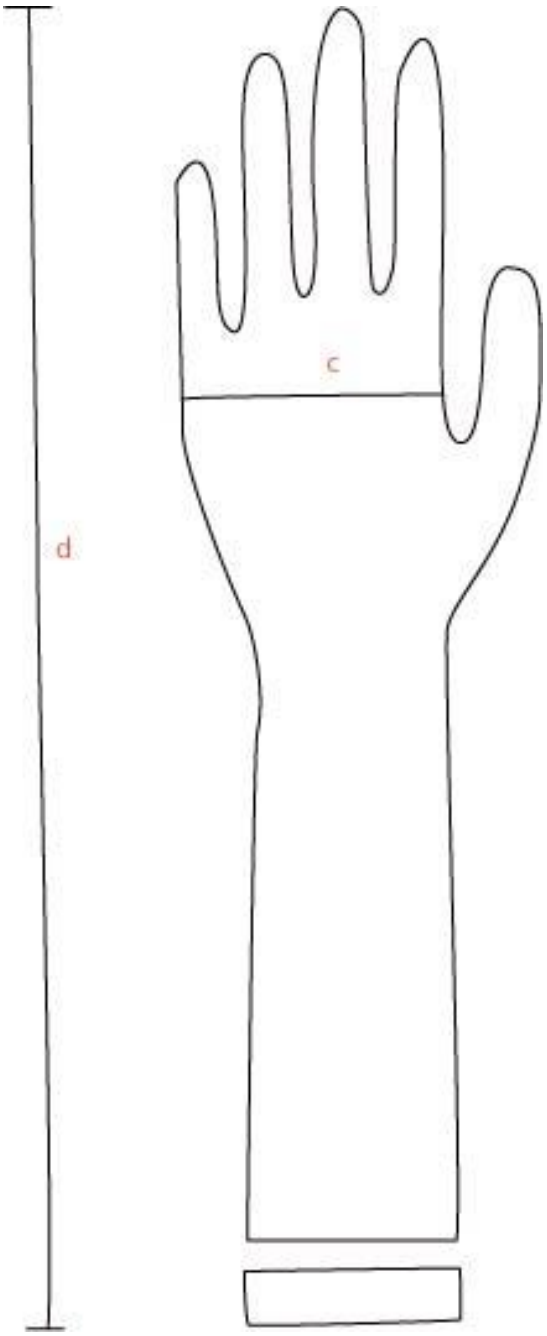


Figure 1: Designation of length (d) and width (c) of gloves

4.4 Product Photographs

Table 2: The colour of gloves for Brand Sritrang Latex powder Free Gloves, Non Sterile

Brand	Product Code	Colour	Picture
1. Sritrang Latex powder Free Gloves, Non Sterile	LO01	Pale Yellow	

SECTION 5 COMPLIANCE WITH PPE REGULATION (EU) 2016/425 ANNEX II EHSR

GENERAL REQUIREMENTS APPLICABLE TO ALL PPE PPE must provide adequate protection against the risks against which it is intended to protect.	-The Glove can use in Industrial activities, that gives protection against low risk solvents & other reagents. This glove protection from potential chemical spills and drips. Not recommended for mechanical risks. Reference Standards: Test Results comply with EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015.
1.1. Design principles 1.1.1. Ergonomics PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.	-The gloves are designed to wear fit and comfortable feel include to user can select the spec of the glove appropriate to wear. Reference Standards : EN 420:2003+A1:2009 , EN455-2 Palm Width (mm.) / Specification - XS: </= 80 - S: 80+/-10 - M: 95+/-10 - L: 110+/-10 - XL: >/=110
1.1.2. Levels and classes of protection 1.1.2.1. Optimum level of protection The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.	--The gloves can be applied with some protection chemical against and not recommended for mechanical risks. Reference Standards: Test Results comply with EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5:2016, EN 16523-1:2015.
1.1.2.2. Classes of protection appropriate to different levels of risk Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.	-We have reference data from the testing results report according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015 in Technical File Document to classify appropriate classes of protection. Reference Standards : The testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
1.2. Innocuousness of PPE 1.2.1. Absence of inherent risks and other nuisance factors PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.	-Pinholes enclosed Inspection level G I for leaks highest concern are non-conformities which prevent correct use of the product. AQL 1.5 for pinholes. Reference Standards : The testing results report comply according to EN 420:2003+A1:2009
1.2.1.1. Suitable constituent materials The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.	-No Pathogenic microorganism -No Protein -No irritation from Chemical Reference Standard : The testing result report according to EN374-2 We have the reference the data from the testing result report such as -Animal Test. (Reference to : ISO 10993),Pathogenic microorganism Test (Reference to : ISO11737-1 and QA.FO.GE.22.024_Microbiological Test)

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.	-irritation from Chemical -We have the control in Production Process and control of glass, plastic, cardboard and sharp for all process. Reference Standard : work instruction -QA.QP.GE.09.001_Production Control -QA.SO.GE.22.010_Control of glass, plastic, cardboard and sharp
1.2.1.3. Maximum permissible user impediment Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.	-The gloves are designed to fit and appropriate to user wear for working in normal condition and no barriers to work. Reference Standards : The testing results report comply according to EN 420:2003+A1:2009
1.3. Comfort and effectiveness	
1.3.1. Adaptation of PPE to user morphology PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.	-We have the Testing Report of Tensile Strength to make sure the Gloves are adequate protection against the risks for which it is intended reference the strength of gloves. (Reference to: EN455-2 and EN 420:2003+A1:2009)
1.3.2. Lightness and strength PPE must be as light as possible without prejudicing its strength and effectiveness. PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.	N/A
1.3.3. Compatibility of different types of PPE intended for simultaneous use If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.	N/A
1.3.4. Protective clothing containing removable protectors Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.	N/A
1.4. Manufacturer's instructions and information In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on: (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;	-The instructions for storage has identified on the packaging. The condition storage in a cool, dry place, avoid ozone, strong light, excessive heat, and humidity. Open box should be shielded from exposure to direct sun or fluorescent lighting. For all detail identify on packaging.

(b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;	-We have reference data from the testing results report according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015 in Technical File Document to classify appropriate classes of protection. Reference Standards : The testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
(c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;	N/A
(d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;	-The Gloves are in class 3 can protect of risk comply with PPE standards. We have testing results report according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015 in Technical File Document to classify appropriate classes of protection. Reference Standards : The testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
(e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;	-The Gloves has Shelf Life 3 Years. We has identify Expiry Date of the gloves on Packaging.
(f) where applicable, the type of packaging suitable for transport;	-We have 2 type of packaging to protect the gloves in transportation process. The gloves are packed in inner box after that we will pack the inner box in to outer box again.
(g) the significance of any markings (see point 2.12);	-We identified the significance of any markings detail on the Packaging. And we has translated all detail into the national language of destination.
(h) the risk against which the PPE is designed to protect;	-We have risk analysis of PPE product to evaluate the risk since designed process to protect the hazard before used. Refer to : Risk Management analysis report QA.SO.GE.14.003_Risk Management Process
(i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;	-We have process to check the compliant with the PPE regulation include to send the product to test according to PPE Regulation. Refer to: EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
(j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;	-We have identified the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE Refer to : Declaration of Conformity
(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;	-We have identified the relevant harmonised standard(s) according to PPE regulation that use in our system in the technical file document Refer to : Technical File Document Testing Report
(l) the internet address where the EU declaration of conformity can be accessed. The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.	-We have identified the address of EU Representative and Manufacturer include to the accesses for contact to the Manufacturer such as internet address on the packaging.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE	
2.1. PPE incorporating adjustment systems If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.	N/A
2.2. PPE enclosing the parts of the body to be protected PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.	N/A
2.3. PPE for the face, eyes and respiratory system Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised. The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.	N/A
2.4. PPE subject to ageing If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging. If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance. Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.	The company has identified the instruction for use include to date of obsolete of product on the package on the packaging. Reference Standards : EN 420:2003+A1:2009 and EN 374-4:2013
2.5. PPE which may be caught up during use Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.	N/A
2.6. PPE for use in potentially explosive atmospheres PPE intended for use in potentially explosive atmospheres must be	N/A

designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite. 2.7. PPE intended for rapid intervention or to be put on or removed rapidly Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment. Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.	
2.8. PPE for intervention in very dangerous situations The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user. The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user. Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.	N/A
2.9. PPE incorporating components which can be adjusted or removed by the user Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.	N/A
2.10. PPE for connection to complementary equipment external to the PPE Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.	N/A
2.11. PPE incorporating a fluid circulation system Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.	N/A
2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the	The company has identified the instruction for use include to date of obsolete and pictograms directly or indirectly relating to health and safety affixed to these types or classes of PPE according to the harmonised pictograms to prevent any misinterpretation to be used. For all details we has state the details on the packaging. Refer to : The details that state on the artwork and the testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016,

foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market. Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.	EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
2.13. PPE capable of signalling the user's presence visually PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.	N/A
2.14. Multi-risk PPE PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.	-The Gloves are in class 3 can protect of risk comply with PPE standards. We have testing results report according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015 in Technical File Document to classify appropriate classes of protection.
3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS	Reference Standards : The testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015
3.1. Protection against mechanical impact	
3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.	N/A
3.1.2. Falls	
3.1.2.1. Prevention of falls due to slipping The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.	N/A
3.1.2.2. Prevention of falls from a height PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any	N/A

PPE component which might cause the user to fall can be expected to occur. Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary. The manufacturer's instructions must specify, in particular, all relevant information relating to: (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user; (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.	
3.1.3. Mechanical vibration PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.	N/A
3.2. Protection against static compression of a part of the body PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.	N/A
3.3. Protection against mechanical injuries PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.	N/A
3.4. Protection in liquids	
3.4.1. Prevention of drowning PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help. PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally. Under the foreseeable conditions of use:	N/A
(a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;	N/A
(b) inflatable PPE must be capable of inflating rapidly and fully. Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:	N/A
(a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound- signalling device;	N/A
(b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;	N/A

(c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.	N/A
3.4.2. Buoyancy aids Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.	N/A
3.5. Protection against the harmful effects of noise PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council (1). 31.3.2016 L 81/80 Official Journal of the European Union EN (1)Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 42, 15.2.2003, p. 38). Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.	N/A
3.6. Protection against heat and/or fire PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.	N/A
3.6.1. PPE constituent materials and other components Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use. Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range. Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE. PPE materials and other components which may be splashed by hot products must also possess sufficient	N/A

mechanical-impact absorbency (see point 3.1). PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.	
3.6.2. Complete PPE ready for use Under the foreseeable conditions of use: (a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold; (b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user. If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user. If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use. The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.	N/A
3.7. Protection against cold PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.	N/A
3.7.1. PPE constituent materials and other components Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures. PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).	N/A N/A
3.7.2. Complete PPE ready for use Under the foreseeable conditions of use, the following requirements apply: (a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on	N/A

the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;	
(b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user. If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use. The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.	N/A
3.8. Protection against electric shock	
3.8.1. Insulating equipment PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions. To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold. Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted. The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.	N/A
3.8.2. Conductive equipment Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.	N/A
3.9. Radiation protection	
3.9.1. Non-ionising radiation PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the	N/A

perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use. To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths. Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor. Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance. The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.	
3.9.2. Ionising radiation	
3.9.2.1. Protection against external radioactive contamination PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use. Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants. Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.	N/A
3.9.2.2. Protection against external irradiation PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation. The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to	N/A

an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2). PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.	
3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents	N/A
3.10.1. Respiratory protection PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration. The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source. The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use. The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user. The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly. In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.	N/A
3.10.2. Protection against cutaneous and ocular contact PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended. To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear. Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests	-The gloves have designed to prevent the surface contact of all or part of the body with dangerous substances and infective agents under the normal working conditions. Reference Standards: The testing results report comply according to EN 420:2003+A1:2009, EN ISO 374-1: 2016, EN 374-2:2014, EN374-4:2013, EN ISO 374-5: 2016, EN 16523-1:2015

with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.	
3.11. Diving equipment The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion. Where the foreseeable conditions of use so require, the diving equipment must comprise the following: (a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2); (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8); (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).	N/A

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SECTION 6 USER INFORMATION AND PRODUCT MARKING

6.1 Symbols on packaging/ Manufacturers Brand

Gloves will be packed in dispensor box

Symbol on packaging

EN 420:2003+A1:2009	Requirements for protective gloves
EN 374	Chemical protection and/or micro-organisms
1935/2004	EC Food regulation
GMP	Good Manufacturing Practice
EN 455	Requirements for medical gloves

Size

☐ Extra-small

☐ Small

☐ Medium

☐ Large

☐ Extra-large

6.2 Packaging Artwork/ User Information (Continuous)

This information is provided on the dispenser box or on carton.

Obsolescence: When stored as recommended will not suffer change in chemical properties for up to two years from date of manufacture. Service life cannot be specified and depends on application and responsibility of user to ascertain suitability of the glove for its intended use.

Storage: Ideally stored in dry conditions in the original package.

Cleaning / Maintenance: Glove should be thoroughly inspected before being worn to ensure no damage is present.

General: The gloves and the raw materials used in their manufacture are not known to be harmful to the wearer. The information contained herein is intended to assist the wearer in selection of personal protective equipment.

Please note: The results of the tests should help in glove selection, however it must be understood that actual conditions of use cannot be simulated and it is the responsibility of the user not the manufacture to determine glove suitability to the intended use. Further information may be obtained from:

Sri Trang Gloves (Thailand) Public Company Limited,110 Kanjanavanit Rd., Pahtong., Hat Yai, Songkhla 90230, Thailand.

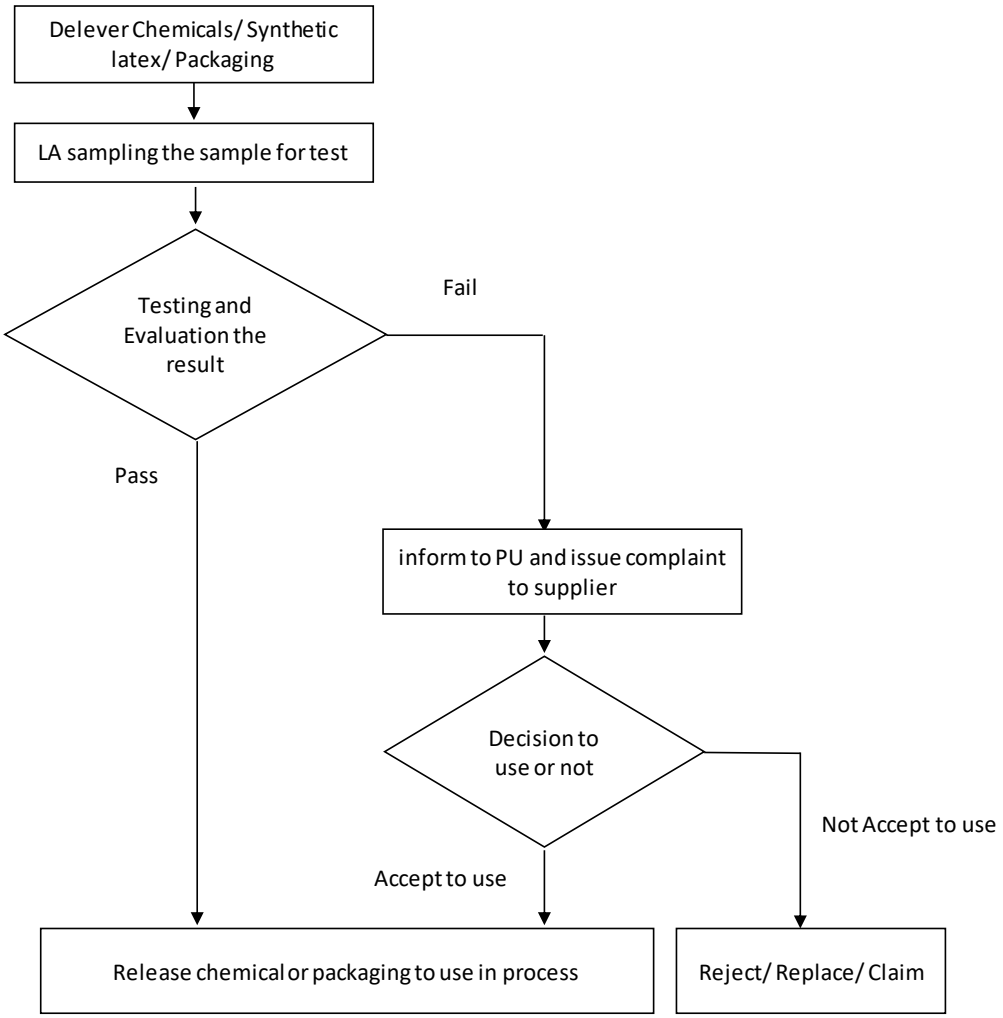
SECTION 7 QUALITY CONTROL PROCEDURES

The company has process to control the quality of product from incoming raw material to finished product and established the procedure for control the process to achieve with the quality target.

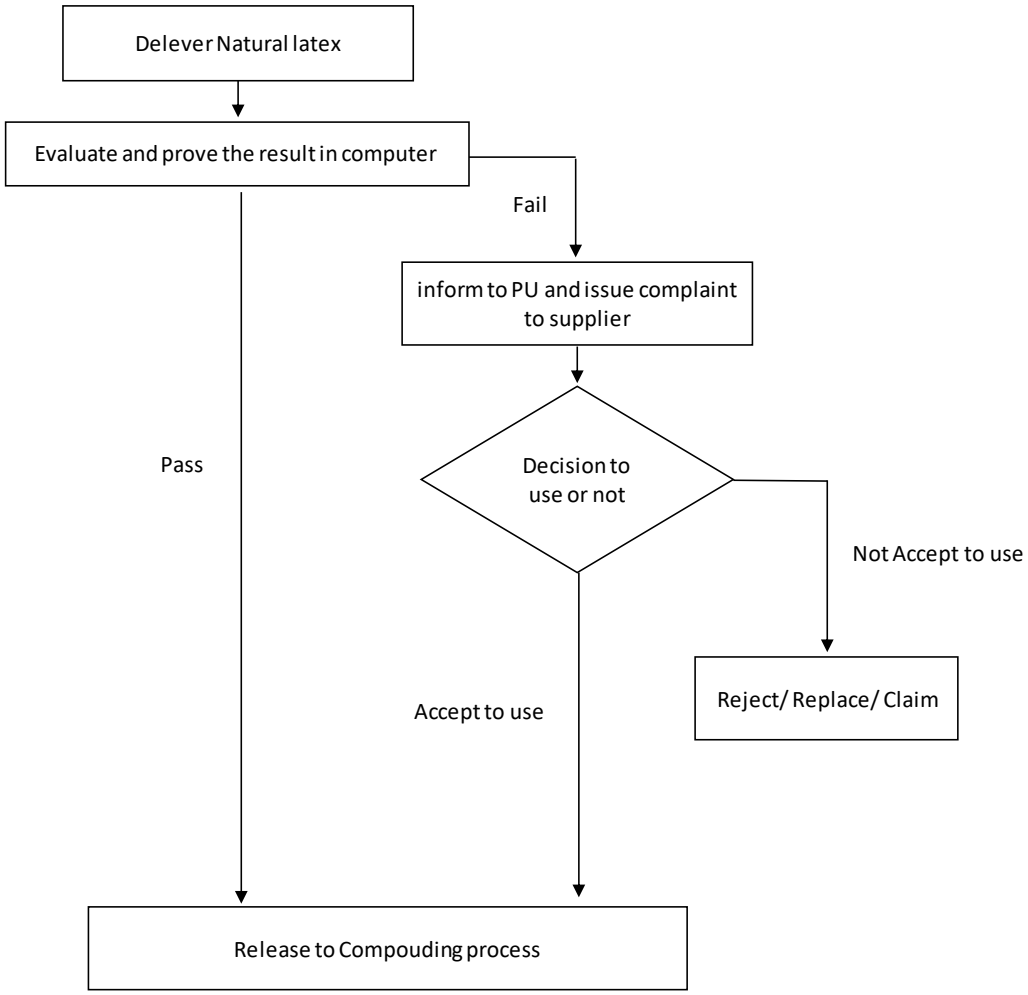
8.1 Quality procedures

8.1.1 Incoming raw material Testing & Inspection process

Chemicals/ Synthetic latex/ Packaging



Natural latex



Refer to: QA.QP.GE.10.003_Incoming raw material Testing & Inspection (STGT-HY)

QA.QP.GE.10.002_Incoming raw material Testing & Inspection (STGT-SR)

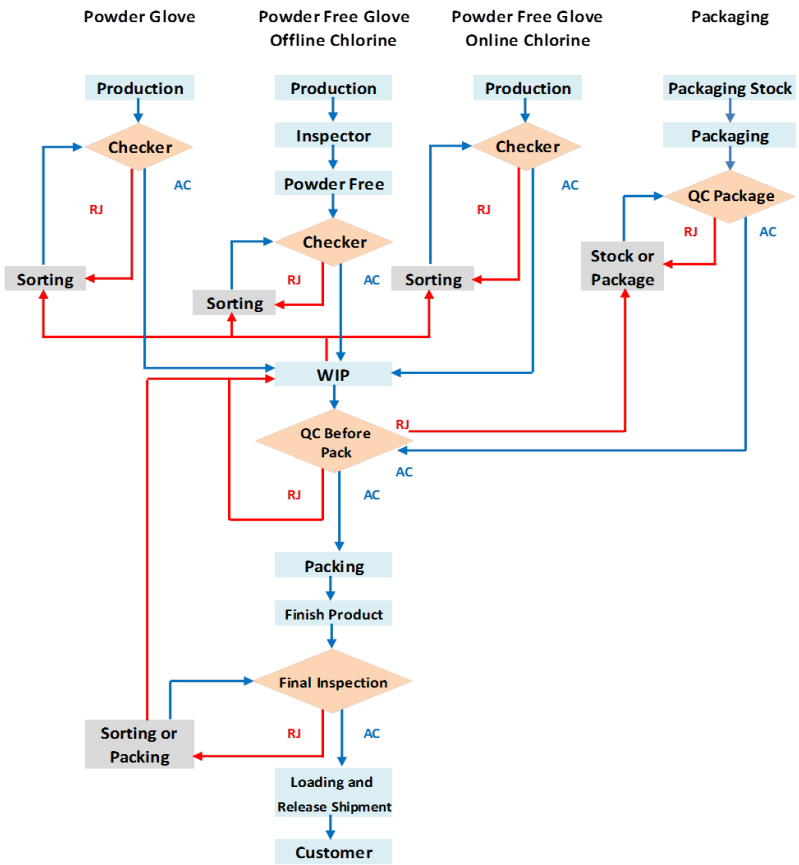
7.1.2 In-process and final inspection sampling plan

The company has process for sampling the glove to testing the quality of each product. For the sampling size is rational according to ISO 2859-1

Inspection Method:

Major defects (pinholes enclosed - Inspection level G I for leaks) highest concern are non-conformities which prevent correct use of the product. AQL 1.5 for pinholes.

Minor defects (Inspection level G I for visual defects aggregated) are non-conformities of lower degree of concern, which do not prevent correct use of gloves AQL 4.0.



Refer to: QA.QP.GE.10.005_In-process and final inspection sampling plan (STGT-HY)

QA.QP.GE.10.003_In-process and final inspection sampling plan (STGT-SR)

SECTION 8 TEST REPORTS

8.1 The testing results of product Latex Powder Free Gloves, Non Sterile (LO01)

Table 3: The result of testing according to EN 420 for product LO01 (for internal code)

Clause /Test	Test Result	Length/mm		Result
	Size	Left	Right	
Glove length, comfort and fit	6	243	242	See note A
	Comment on fit : Satisfactory			
	7	243	242	
	Comment on fit : Satisfactory			
	8	243	242	
	Comment on fit : Satisfactory			
	9	238	241	
	Comment on fit : Satisfactory			
	10	248	242	
	Comment on fit : Satisfactory			
Dexterity	Size	Minimum pin diameter/mm		Level 5
	6	5.0		
	7	5.0		
	8	5.0		
	9	5.0		
	10	5.0		

Note A: Where the gloves do not meet the minimum length as EN 420 requirements specific because the glove was produced for both of the examination and PPE glove so the size of glove is refer to EN 455-2.

pH value test by ISO 3071:2005 (water extraction)

Test	EN 420 : 2003+A1:2009 Requirements	Result
Determination of pH Value, pH value	> 3.5 and <9.5	6.9

Determination of PAHs

Product Latex Powder Free online chlorination Gloves, Non Sterile (LO01)	PAHs detected	Pass/Fail
LO01	< 0.2 (of each PAH listed in the appendices)	Pass
Requirements: REACH 1907/2006 annex XVII entry number 50	< 1 mg/kg of each PAH listed in the appendices	-

Table 4: The result of testing according to EN 374-2:2003 for product LO01 (for internal code)

Product : Latex Powder Free Gloves, Non Sterile (LO01)			
Test	**EN 374-2:2003 Requirements**	**Number tested (pieces)**	**Result**
I. Air leak test (type test)	No Leakage	4	Passed
II. Water leak test (Type test)	No Leakage	4	Passed

For The result of testing (Table 5) Glove from a single lot shall be sampled and inspection in accordance with ISO2859.The inspection levels and acceptable quality levels (AQL) shall comply with those given in the table below.

Performance Level	Acceptable Quality Level Unit	Inspection Levels
Level 3	<0.65	G1
Level 2	<1.5	G1
Level 1	<4.0	S4

Table 5: The result of testing according to EN 374-4:2013 for product LO01 (for internal code)

Chemical	Mean degradation / %
Methanol (CAS: 67-56-1)	-28.4
Acetone (CAS: 67-64-1)	11.6
Acetonitrile (CAS: 75-05-8)	-44.9
Dichloromethane (CAS: 75-09-2)	100
Carbon disulphide (CAS: 75-15-0)	100
Toluene (CAS: 108-88-3)	95.7
Diethylamine (CAS: 109-89-7)	97.5
Tetrahydrofurane (CAS: 109-99-9)	97.8
Ethyl acetate (CAS: 141-78-6)	54.8
n-Heptane (CAS: 142-82-5)	36.7
40%Sodium hydroxide (CAS: 1310-73-2)	-72.4
96% Sulphuric acid (CAS: 7664-93-9)	92.9
65% Nitric acid (CAS: 7697-37-2)	20.9
99% Acetic acid (CAS: 64-19-7)	-17.8
25% Ammonium hydroxide (CAS: 1336-21-6)	-346.9
30% Hydrogen peroxide (CAS: 7722-84-1)	-64.1
37% Formaldehyde (CAS: 50-00-0)	-81.7

Table 6: The result of testing according to EN 374-5:2016 for product LO01 (for internal code)

Test specimen	Number of PFU/ ml of assay fluid	Results
1	< 1 (no penetration)	Pass
2	< 1 (no penetration)	Pass
3	< 1 (no penetration)	Pass

Pass-no penetration of bacteriophages thought the specimen

Table 7: The result of testing according to EN16523-1:2015 for product LO01 (for internal code)

Chemical	Performance level
Methanol (CAS: 67-56-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Acetone (CAS: 67-64-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Acetonitrile (CAS: 75-05-8)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Dichloromethane (CAS: 75-09-2)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Carbon disulphide (CAS: 75-15-0)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Toluene (CAS: 108-88-3)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Diethylamine (CAS: 109-89-7)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Tetrahydrofuran (CAS: 109-99-9)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
Ethyl acetate (CAS: 141-78-6)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
n-Heptane (CAS: 142-82-5)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
40% Sodium hydroxide (CAS: 1310-73-2)	4
96% Sulphuric acid (CAS: 7664-93-9)	1
25% Ammonium hydroxide (CAS: 1336-21-6)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
99% Acetic acid (CAS: 64-19-7)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
65% Nitric acid (CAS: 7697-37-2)	1
15% Formaldehyde (CAS:50-00-0)	6
37% Formaldehyde (CAS: 50-00-0)	6
30% Hydrogen peroxide (CAS: 7722-84-1)	6

8.2 The summary test report of product Latex Powder Free online chlorination Gloves, Non Sterile (LO01)

Product code or material reference	Standard / Clause	Report Number
Latex Powder Free online chlorination Gloves, Non Sterile	EN 420:2003 + A1:2009 clauses 5.1 Sizing & 5.2 Dexterity only	SPC0250643/1641 Issue 2
Latex Powder Free online chlorination Gloves, Non Sterile	BS EN 420:2003+A1:2009 Clause 4.3.2 pH value	SPC0250643/1641/SMcD/AA
Latex Powder Free online chlorination Gloves, Non Sterile	EN 374-2:2014	SPC0250643/1641 Issue 2
Latex Powder Free online chlorination Gloves, Non Sterile	REACH 1907/2006 annex XVII entry number 50	SPC0250643/1641/SMcD/AA
Latex Powder Free online chlorination Gloves, Non Sterile	BS EN 374-4:2013	CHM0259121/1725/EN/SMcD/AA
Latex Powder Free online chlorination Gloves, Non Sterile	BS EN ISO 374-5:2016 (ISO 16604:2004)	CHM0259121/1725/EN/SMcD/BB
Latex Powder Free online chlorination Gloves, Non Sterile	EN 16523-1:2015	SPC0250643/1641/EN/C Report no.64641

SECTION 9 DESIGN CALCULATIONS, INSPECTIONS AND EXAMINATIONS.

Product code or material reference	Standard / Clause	Reference to design calculation, inspection or examination report
Latex Powder Free online chlorination Gloves, Non Sterile (LO01)	BS EN 420:2003+A1:2009 clauses 5.1 Sizing& 5.2 Dexterity	Refer to report no. SPC0250643/1641 Issue 2
	BS EN 420:2003+A1:2009 Clause 4.3.2 pH value	Refer report no. SPC0250643/1641/SMcD/AA
	EN 374-2:2014	Refer to report no. SPC0250643/1641 Issue 2
	REACH 19707/2006 annex XVII entry number 50	Refer to report no. SPC0250643/1641/SMcD/AA
	BS EN 374-4:2013	Refer to report no. CHM0259121/1725/EN/SMcD/AA
	BS EN ISO 374-5:2016 (ISO 16604:2004)	Refer to report no. CHM0259121/1725/EN/SMcD/BB
	BS EN 16523-1:2015	Refer to report no. SPC0250643/1641/EN/C Report no.64641