TECHNICAL FILE

POWDERED LATEX EXAMINATION GLOVES

SUPERMAX GLOVE MANUFACTURING SDN BHD

LOT 38, PUTRA INDUSTRIAL PARK
BUKIT RAHMAN PUTRA
47000 SUNGAI BULOH, SELANGOR, MALAYSIA.
TEL: 03-61452328
FAX: 03-61562191

TECHNICAL FILE

POWDERED LATEX EXAMINATION GLOVES

DOCUMENT NO. : SGM-FTF-1A

Prepared by : Rosnita Asst. QA Manager	Approved by : Yap Peak Geeh QA & Regulatory Affair Manager
Date : 9th January 2020	Date : 9th January 2020

TABLE OF CONTENTS

1.0 DETAILS OF MANUFACTURER

1.1 Manufacturer :

Maxter Glove Manufacturing Sdn. Bhd.
Lot 6070 Jalan Haji Abdul Manan,
6th Miles Off Jalan Meru,
41050 Klang, Selangor, Malaysia

Tel: 603-33929888
Fax: 603-33923328

1.2 Our Authorized Representative in Europe:

Supermax Healthcare (Europe) Limited
38 Main Street,
Swords,
County Dublin
Ireland
K67 E0A2

2.0 DESCRIPTION OF PRODUCT

2.1 Device Family : Powdered Latex Examination Gloves

Classification : Class I, Non- sterile
Conformity : Annex IV of Medical Device Regulation (EU) 2017/745, declaration of conformity
GMDN Code : 47173

Powdered latex examination glove is classified as Class I medical device as per Rule 5, Annex VIII of Medical Device Regulation (EU) 2017/745.

2.2 Brief Description

The powdered latex examination glove is made from 100% natural rubber, ambidextrous and non-sterile. It is treated with modified corn starch which is to facilitate the user in donning the glove and as well as to prevent the glove surface from sticking to each other.

2.3 Intended Use

The powdered latex examination glove is a medical device, which protects the hand or part of the hand of the user.

The main function of wearing gloves is to protect the wearer against contamination of infectious materials particularly viruses, bacteria, infected blood and body fluids. Thus, the single most important criterion in gloves selection is barrier protection, as defined by all users, including physicians, dentists, medical and non-medical workers and researchers.

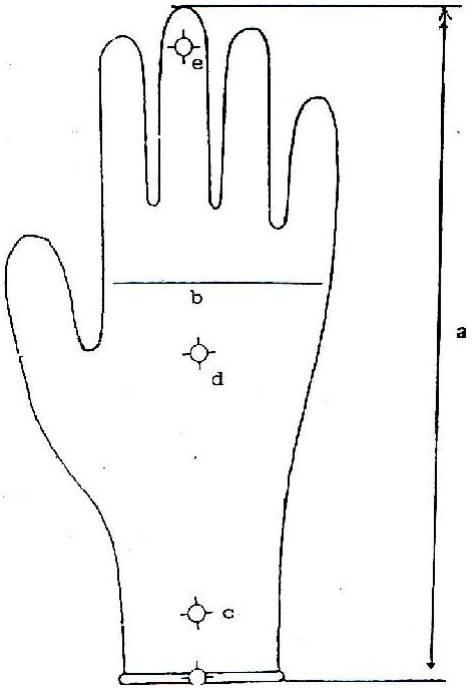
The next most important criterion are strength, fit, comfort and dexterity, that is the ability for the glove to stretch, remain soft and comfort to the hand due to the thickness and elastomeric nature of the latex glove.

It is intended for single use only.

The powdered latex examination gloves are usually used for conducting medical examination, dentistry, clinical examination, diagnostic and therapeutic procedures and also for laboratory purposes.

DESIGN DRAWING

Powdered Latex Examination Glove



Indicators

a. Length of glove
b. Palm width
c. Cuff thickness (15 +/- 5 mm from the cuff end)
d. Palm thickness (approximately on the center of the palm opposite the thumb crotch)
e. Thickness of middle finger tip (13 +/- 3 mm from the extreme tip)

DESIGN SPECIFICATIONS

Size	Extra-Small	Small	Medium	Large	Ex-Large
Width Tolerance	70-79 mm	80-89 mm	90-99 mm	100-109 mm	110-119 mm
Overall Length	Min 240 mm	Min 240 mm	Min 240 mm	Min 240 mm	Min 240 mm
Thickness At Palm	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm
Thickness At Finger	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm	Min 0.08 mm

2.4 TENSILE STRENGTH

2.4.1 The tensile property at break shall comply with the requirements provided in Table SGM-FTF-1A (I) physical properties which is in accordance to ASTM D3578.

Physical Properties	Requirements
Minimum tensile strength at break before accelerated aging	≥ 18 MPa
Minimum tensile strength at break after accelerated aging	≥ 14 MPa
Minimum elongation at break before accelerated aging	≥ 650%
Minimum elongation after accelerated aging	≥ 500%

TABLE SGM-FTF-1A (I) PHYSICAL PROPERTIES

2.4.2 Tensile Strength at break after accelerated ageing involve gloves being aged for 7 days at $70^{o}C \pm 2\ ^{o}C$ in air, in a normal oven.

2.5 PROTEIN TESTING

2.5.1 A variety of methods exists for protein determination. The EN 455-3: 2006 test method has been developed and validated as the best procedure currently available for quantification of aqueous extractable protein in gloves containing natural rubber. This procedure is based upon a modified Lowry assay whereby the protein of an aqueous extract is purified by precipitation and quantified colorimetrically.

2.5.2 The main advantages of the method are

(a) Widespread use and availability as well as relative ease of performance.

(b) The colour development is rapid and the resultant complexes are stable.

(c) The problems of interfering substances are minimized by a precipitation step.

2.6 BIOCOMPATIBILITY

2.6.1 Dermal sensitization is performed to demonstrate the potential of the device for eliciting a delayed hypersensitivity (Type IV) immunological response through its contact with the skin. The reaction is due primarily to substances that could leach out of a material. Guinea pigs are used because they have been shown to be the best animal model for human allergic contact dermatitis.

2.6.2 Insult Patch Test is to determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergenic contact sensitization.

3.0 LIST OF HARMONISED STANDARDS

3.1 The powdered latex examination gloves are manufactures in a strict GMP environment with a certified quality management system to ISO9001 and ISO 13485.

3.2 The powdered latex examination gloves meet the in-house requirements as well as the harmonised standards of EN455.

3.3 Systematic procedures have been established in complying with the relevant regulatory requirements stated in the following international standards.

Document No.	Title of Document
ISO 9001	Quality management systems - Requirements
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
BS EN ISO 14971	Medical devices – Application of risk management to medical devices
ASTM D3578	Standard Specification for Rubber Examination Gloves
EN 455-1	Medical gloves for single use - Part 1 : Requirements and testing for freedom from holes
EN 455-2	Medical gloves for single use - Part 2: Requirements and testing for physical properties
EN 455-3	Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
EN 455-4	Medical gloves for single use Part 4: Requirements and testing for shelf life determination
EN 10993 – Part 1	Biological evaluation of medical devices – Part 1: Evaluation and testing
EN 420	Protective gloves – General requirements and test methods
EN 1041	Medical devices – Information supplied by the manufacturer
EN 374-2	EN 374- Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

4.0 LABELLING ON GLOVE PACKAGING

4.1 Marking of the packaging material shall be in accordance with the labelling requirement of Medical Device Regulation (EU) 2017/745 Annex I and the graphical symbols use in the labelling shall be accordance to ISO 15223-1.

4.2 The CE mark will appear as shown in Medical Device Regulation (EU) 2017/745 Annex V, on, where appropriate, the unit, packaging and instruction for use.

4.3 The CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

4.4 Name and Full Address of Manufacturer
Supermax Glove Manufacturing Sdn Bhd
Lot 38, Putra Industrial Park,
Bukit Rahman Putra,
47000 Sungai Buloh, Selangor , Malaysia
Tel: 603-61452328
Fax: 603-61562191

4.5 Glove designation (commercial name)
SUPERMAX Latex Medical Examination Gloves, Powdered

4.6 Size designation :- X- Small, Small, Medium, Large, X- Large

4.7 Date of obsolescence.
Date of manufacture : 2020-01. Valid for 05 years from the date of manufacture. Date of expiry: 2025-01.

4.8 Country of Origin
Example :-
Made In Malaysia

4.9 The “lot number” is preceded by a serial number.
Example :-
Lot Number – 6 0 02 0 11988
Where:-
6 - Maxter Glove Manufacturing Sdn Bhd
0 - Last digit of the year (0 – 2020, 1 – 2021…)
2 - 2nd week of the year.
0 - size (0- extra small, 1- small, 2- medium, 3- large, 4- extra large)
11988 - running number.

4.10 Net Quantity of Contents Statement

The label shall contain a statement of net quantity of contents in terms of numerical count.

Example:-

Quantity: 100 Gloves by Weight

4.11 If appropriate, warnings against problems likely to be encountered shall be mentioned. A list of substances contained in the glove which are known to cause allergies.

EXAMPLE:-

Caution: Users should consider the circumstances of use in deciding whether to remove any residual powder on gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.

Warning: Isolated cases of allergic reactions to latex rubber or powder have been reported. If you experience a reaction to this product, discontinue use immediately and consult your physician. This product contains Natural Rubber Latex which may cause allergic reactions in some individuals.

4.12 Storage conditions.

Store in cool dry place, avoid excessive heat (40 ^{o} C, 104 ^{o} F). Open box should be shielded from exposure to direct sun or fluorescent lighting.

4.13 Type of packaging suitable for transport.

- 100 pcs /dispenser
- 10/20 dispensers per carton

5.0 PRODUCTION OF POWDERED LATEX EXAMINATION GLOVES

5.1 INCOMING RAW MATERIALS

5.1.1 When high ammonia latex is delivered to the factory, the dispatch note detailing the quantity, the seal numbers and the tanker registration shall be checked against the actual seals and tanker.

5.1.2. The certificate of analysis (COA) shall be checked against company latex specification.

5.1.3 Latex shall be rejected if : -

(i) it is found not to meet specifications,
(ii) if seals have been tampered with,
(iii) if the delivery does not correspond with the dispatch note, and
(iv) if the gross amount on Maxter factory's weighbridge ticket does not fall within -100 kg of the supplier's stated amount.

5.1.4 Incoming chemical shall be placed in the factory's holding area, examined for external sign of damage, and verified for quantity.

5.1.5 Acceptance of the supplied chemical shall be indicated by a signing and dating on the appropriate delivery documentation. The verifying chemist shall place the "approved goods tag" on the accepted chemical before it is stored for use. Chemical shall be accepted on the following terms:

(i) There is no damage to the goods
(ii) The supplier certificate of analysis is in compliance with factory specifications
(iii) The documentation is complete
(iv) Should the quantity delivered not tally with delivery documents, the factory purchasing department shall be informed so as to follow up on the remainder of goods

5.2 LATEX COMPOUNDING

5.2.1 The raw latex is compounded with various components that are essential to the vulcanization process. These components include: sulphur, zinc oxide, accelerator, pigments and stabilizers (antioxidants). These components are water-insoluble and are reduced to the finest possible dispersions, prior to being incorporated into the latex compound.

5.2.2 At least four hours after compounding a batch of latex, a sample is taken and tested for total solid content (TSC). If the TSC is not within the required range, either raw latex or water is added accordingly. A subsequent TSC check is then performed.

5.2.3 After checking the TSC, the compounded latex is stored to permit a degree of pre-vulcanization/maturation. The compound is then gently stirred for at least 24 hours and a test is performed to judge the degree of maturation and suitability of that particular batch of compounded latex for processing. If the compounded latex is found to be unsuitable, either re-blending or the addition of more accelerators may be required. Compounded latex suitable for processing is transferred to the latex dip tank.

5.3 PRE-TREATMENT OF FORMERS - COAGULANT DIP

The formers are washed in acid and warm rinsing water before being dipped into the warm coagulant solution. The coagulant solution facilitates deposition of the latex film onto the ceramic formers. The solution is topped automatically to ensure that the concentration level does not vary significantly due to either evaporation or the dipping process. In addition, tests are performed to guarantee that the solution's TSC is within the acceptable range. The coagulant tank is equipped with a stirrer and nozzle to maintain the coagulant solution in suspension.

5.4 COAGULANT OVEN

To partially dry the coagulant-coated formers with direct gas heating in conjunction with infra-red rays

5.5 LATEX DIP

Formers are dipped once into the latex dip tank to achieve the specified thickness of latex. They are then slowly withdrawn in such a way as to leave a uniform deposit of latex on them. The latex dip tank is outfitted with a jacketing-type system that circulates cold water around the outside of the tank to permit temperature control of the latex. It is also equipped with a stirrer to keep all components of the compound in suspension thereby preventing the formation of surface skim due to evaporation.

5.6 GELLING OVEN

Gelling of the latex film is effected using a gelling oven with direct gas heating in conjunction with infra-red rays.

5.7 WET GEL LEACHING

Leaching is an operation performed to remove water-soluble proteins (associated with latex allergy), and is necessary to produce gloves with a low protein content for reduced allergic response. The temperature of the leaching water is maintained at $\geq 40^{\circ}C$. The leaching water is kept clean via regular changing and by allowing for a constant overflow. Leaching time is approximately 60 seconds.

5.8 BEADING

Glove beading is achieved mechanically with small rotating brushes that roll down a thin film of rubber at the cuff area.

5.9 VULCANIZATION

Formers pass through an oven heated to varying temperatures between $95^{o}C$ - $120^{o}C$. The temperature of the oven increases progressively along its length. Vulcanization takes place as the formers pass through this increasing temperature zone from one end of the oven to the other.

5.10 POST-CURE LEACHING

In addition to wet gel leaching, post-cure leaching is also used because a substantial amount of water-soluble proteins come to the glove surface upon drying and vulcanisation. The dry film leaching (post-cure) is used to further remove such extractable proteins. The leaching water is maintained at $\geq 40^{o}C$ and is equipped with an overflow. Leaching time is approximately 90 seconds.

5.11 SLURRY DIP

The gloves are coated with modified cornstarch (USP grade).
Tests are performed on the slurry dip solution every two hours to ensure that solution specifications are met and have not become unbalanced in any way. The slurry is kept at $\geq 35^{o}C$.
A circulating pump is used to prevent powder sedimentation.

5.12 SLURRY DRYING OVEN

The gloves dry as they progress along the length of the oven.

5.13 STRIPPING

The gloves are air stripped from the formers, stack and pack by the auto stacking machine.

6.0 QUALITY CONTROL OF PRODUCT

6.1 BRIEF SUMMARY OF QUALITY

6.1.1 ON-LINE INSPECTION

The weight, length and thickness of the gloves shall then be verified two-hourly to guarantee that they meet company specifications as provided in Table SGM-FTF-1A (II). Any process deficiencies detected shall be corrected immediately.

Dimension (mm)	Extra-Small	Small	Medium	Large	Extra-Large	Tolerance
Length	240 mm	240 mm	240 mm	240 mm	240 mm	Min.
Width	70-79 mm	80-89 mm	90-99 mm	100-109 mm	110-119 mm	-
Thickness (Single wall)						
Palm	0.08 mm	0.08 mm	0.08 mm	0.08 mm	0.08 mm	Min.
Finger	0.08 mm	0.08 mm	0.08 mm	0.08 mm	0.08 mm	Min.

TABLE SGM-FTF-1A (II) DETAILED GLOVE DIMENSION

6.1.2 QA-OFF-LINE INSPECTION

Purpose : To identify and separate bags of gloves that are either within or beyond AQL as per ISO 2859-1:1999.

Sampling : Sampling Procedure ISO 2859-1:1999 General Inspection Level G1,Single sampling shall be utilized for normal inspection.

Equipment : A nozzle through which compressed air is supplied. Ruler to be used, AQL 1.5 stamp and AQL 2.5 stamp.

Procedure :

(a) Gloves are ready for testing after they have been weighed and placed into white polypropylene woven bags.

(b) Each batch of gloves (8 bags) contains approximately 10,001-35,000 pcs gloves. According to inspection level G1, a sample size of 125 pieces is required. Thus, for sampling purposes, this number of gloves is picked at random from the batch of gloves.

(c) The sample gloves are then inflated to facilitate detection of defects.

(d) The inspection criteria employed is based in the normal sampling plan and is illustrated below :

(i) Criteria Defect - Pinhole/Tear

0,1,2,3	Pinhole/tear found = Pass AQL 1.0 Gloves are sent for direct packing for medical sector.
4,5	Pinhole/tear found = Pass AQL 1.5 Gloves are sent for direct packing for medical sector.

6,7 Pinhole/tear found = Pass AQL 2.5
Gloves are sent for AQL 2.5 order.

>7 Pinhole/tear found
Send gloves for 100% pump test (rework).

(ii) Major Visual Defect (other than pinhole/tear)

0-7 Major defects found = pass AQL 2.5 (as required)
Gloves are sent for the direct packing.

>7Major defects found
Gloves are sent for 100% visual check (rework).

(iii) Visual Minor Defect

0-10 Minor defect(s) found = Pass AQL 4.0
Gloves are sent for direct packing.

>10 Minor defects found
Gloves are sent for 100% visual check (rework).

6.1.3 <u>100% PUMP TEST (REWORK PROCEDURE)</u>

Purpose: To segregate gloves that failed the pinhole/tear inspection during the QA-OFF-Line. These gloves are separated into first grade, second grade and reject.

Equipment: Air nozzle through which compressed air is supplied.

Procedure:

(a) Gloves are pumped full of air piece by piece to facilitate detection of pinholes, tears and other defects. Gloves with defects shall be segregated from first grade gloves, into second grade or reject grade.

(b) After finishing a bag of gloves, the quantities of first grade, second grade and reject gloves are recorded.

(c) Segregated first grade gloves shall be inspected for released by the QA-On-QC operator based on an inspection procedure similar to the QA-Off-Line inspection.

6.1.4 100% VISUAL CHECK (REWORK PROCEDURE)

Purpose: To visually separate gloves into first grade, second grade and reject grade.

Procedure:

(a) The QC operator shall visually inspect each glove. Gloves with defects shall be segregated from first grade gloves and placed into second grade (green plastic bag) or reject (clear white plastic bag) grade as applicable.

(b) Upon completion of the visual check, all first grade, second grade and reject gloves are weighed and recorded.

(c) The segregated first grade gloves shall then be inspected for release to the packing department by QA-on-QC operator based on a sampling procedure similar to that of the QA-Off-Line inspection.

6.2 QA-ON-PRE-SHIPMENT (PALLET CHECK/INSPECTION ON PACKED GOODS)

Purpose: To confirm packed goods meet both company specification and customer requirements prior to shipment.

Sampling: Sampling procedure ISO 2859-1:1999 Special inspection level S-3 Single sampling plan for normal inspection.

Equipment: A nozzle through which compressed air is supplied.
Dial micrometer thickness gauge. Ruler.
Water tight test apparatus.

Procedure:

(a) Water tight test

Sample size : 32 pieces (according to ISO 2859-1:1999 sampling procedure, inspection level S-3 and single sampling plan for normal inspection.

Criteria applied is as follows :

0,1 Pinhole/tear found = Pass AQL 1.5 and AQL 2.5 shipment requirement.

2 Pinhole/tears found = pass AQL 2.5 Shipment requirement only.

>2 Pinhole/tears found = Reject and repack cartons with new set of gloves. Former gloves shall be reworked by the QC operators.

(b) Visual test

Sample size : 32 pieces (according to inspection level S-3 and normal sampling plan)

(i) Major Visual Defect

0,1,2 Major defect found = Pass AQL 2.5 (required)

>2 Major defect found = Reject and repack cartons with new set of gloves.

(ii) Minor Visual Defect

0,1,2,3 Minor defects found = Pass AQL 4.0 (required)

>3 Minor defects found = Repeat this procedure from step (a).

(c) Dimension Check

Three (3) pieces are randomly chosen from the sample in the visual section. These gloves are checked for length, width and thickness with the use of a ruler and dial thickness gauge.

In-house criteria is as follows :

0 Defect found = Pass

1 Defect found = Reject and replace gloves in the cartons affected Repeat the entire procedure from step (a). If positive results are obtained, the pallet has passed. If negative results are obtained, the entire pallet of gloves shall be replaced by a new set.

(d) Glove Count

In-house criteria is as follows :

100 pieces of gloves per dispenser ($\pm$ 2 pieces)

50 pieces of gloves per dispenser ($\pm$ 1 piece)

25 pieces of gloves per dispenser ($\pm$ 1 piece)

If beyond criteria, every dispenser in the pallet shall be weighed and checked.

6.3 QA-ON-FINAL CHECK (QA INSPECTION BASED ON SIZE BREAKDOWN)

Purpose : To guarantee that packed goods of every size are of good quality and meet both company specifications and customer requirements prior to delivery.

Equipment : Water tight test equipment
Tensile test machine

Watertightness and tensile property testing shall be undertaken in accordance with customer requirements.

(i) European Requirement

(a) Watertightness

EN 455-1	: Medical Gloves for Single Use. Part 1. Specification for Freedom from Holes.
Inspection Level	: GI, Single normal sampling
AQL	: 1.5
Sampling basis	: Size by size

(b) Tensile Properties

ASTM D3578	: Standard Specification for Rubber Examination Gloves Specification for Physical Properties.
Inspection Level	: S2, AQL4.0
Sampling basis	: Entire consignment.

For tensile properties test:-

(i) Unaged Sample	: Tensile properties of unaged gloves shall pass the given criteria before release of packed goods for loading into container.
(ii) Aged Sample	: If tensile properties of aged gloves fail the criteria, the container shall be recalled in accordance to SGM-WI-14 Recall of goods.