TECHNICAL FILE

POWDER FREE NITRILE EXAMINATION GLOVES

MAXTER GLOVE MANUFACTURING SDN. BHD.

LOT 6070 JALAN HAJI ABDUL MANAN,
6TH MILES OFF JALAN MERU, 41050 KLANG
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POWDER FREE NITRILE EXAMINATION GLOVES

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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 : Powder Free Nitrile Examination Gloves
Classification : Class I, Non- sterile
Conformity : Annex IV of Medical Device Regulation (EU) 2017/745, declaration of conformity
GMDN Code : 56286

Powder free nitrile 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 powder free nitrile examination glove is made from 100% synthetic rubber, ambidextrous and non-sterile. It is treated with chlorine 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 powder free nitrile 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.

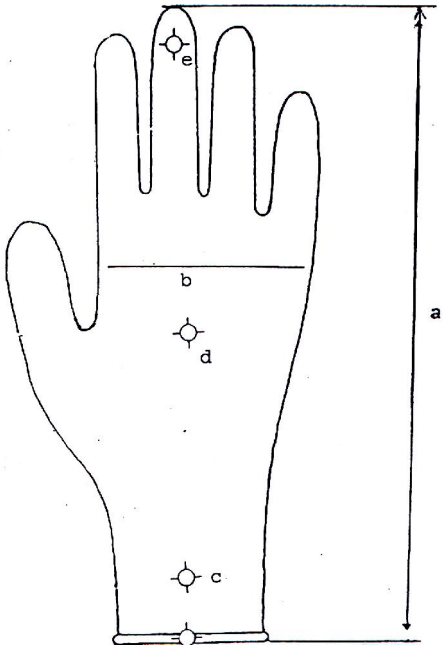
The next most important criterion are strength, fit, comfort and dexterity, that is the ability for the glove to stretch, remain soft and comfort to the hand due to the thickness and elastomeric nature of the latex glove.

It is intended for single use only.

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

DESIGN DRAWING

Powder Free Nitrile Examination Glove



Indicators

a. Length of glove
b. Palm width
c. Cuff thickness (25 +/- 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

Dimension	**Extra-Small**	**Small**	**Medium**	**Large**	**Extra-Large**	**Tolerance**
Length (mm)	240	240	240	240	240	Min.
Width (mm)	70-79	80-89	90-99	100-109	110-119	-
Thickness (Single Wall)						
Cuff (mm)	0.05	0.05	0.05	0.05	0.05	Min.
Palm (mm)	0.05	0.05	0.05	0.05	0.05	Min.
Finger (mm)	0.09	0.09	0.09	0.09	0.09	Min.

2.4 TENSILE STRENGTH

2.4.1 The tensile property at break shall comply with the requirements provided in Table MGM-FTF-3B(I) Force at Break which is in accordance to EN455-2.

Physical Properties	Requirements
Minimum force at break during shelf life	$\geq$ 6 N
Minimum force at break after accelerated ageing	$\geq$ 6 N

TABLE MGM-FTF-3B (I) FORCE AT BREAK

2.4.2 Physical properties 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 BIOCOMPATIBILITY

2.5.1 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.

2.5.2 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 powder free nitrile examination gloves are manufactured in a strict GMP environment with a certified quality management system to ISO9001 and ISO 13485.

3.2 The powder free nitrile 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
EN ISO 14971	Medical devices – Application of risk management to medical devices
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 1041	Medical devices – Information supplied by the manufacturer
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
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

4.5 Glove designation (commercial name)
MAXTER Nitrile Medical Examination Gloves, Powder Free

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 - 8 0 02 3 11268
Where:-
8 - Maxter Glove Manufacturing Sdn. Bhd.
0 - last digit of the year (0 – 2020, 1 – 2021…)
02 - 2nd week of the year.
3 - size (0- extra small, 1- small, 2- medium, 3- large, 4- extra large)
11268 - 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.
EXAMPLE:-
Primary Material- The gloves are not made of Natural Rubber Latex.

Warning: Components used in making gloves 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 POWDER FREE NITRILE EXAMINATION GLOVES

5.1 INCOMING RAW MATERIALS

5.1.1 When synthetic nitrile 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 nitrile specification.

5.1.3 Bulk synthetic nitrile 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 NITRILE COMPOUNDING

5.2.1 The synthetic nitrile is compounded with various components that are essential to the vulcanization process. These components include: sulphur, zinc oxide, accelerator, pigments (Titanium Dioxide & blue or orange pigment depend on the colour of the gloves) and stabilizers. These components are water-insoluble and are reduced to the finest possible dispersions, prior to being incorporated into the nitrile compound.

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

5.2.3 After checking the TSC, the compounded nitrile is stored to permit a degree of pre-vulcanization/maturation. The compound is then gently stirred for at least 24 hours. Compounded nitrile suitable for processing is transferred to the nitrile 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 NITRILE DIP

Formers are dipped once into the nitrile dip tank to achieve the specified thickness of nitrile latex. They are then slowly withdrawn in such a way as to leave a uniform deposit of nitrile on them. The nitrile 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 nitrile. 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 nitrile 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 substances and is necessary to produce "cleaner" gloves with reduced allergic response. The temperature of the leaching water is maintained at < 70 °C. The leaching water is kept clean via regular hanging 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 60^{o}C - 170^{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 excess chemicals (associated with allergy), and is necessary to produce "cleaner" gloves with reduced allergic response. The leaching water is maintained at 60 ^{o}C-70^{o}C and is equipped with an overflow. Leaching time is approximately 90 seconds.

5.11 DRYING OVEN

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

5.12 CHLORINE TANK

To reduce surface drag inside gloves (refer to donning side). The temperature shall be kept ≤ 40 ºC and is equipped with an overflow. The Chlorine content shall be maintained within 300-1000 ppm.

5.13 STRIPPING

The gloves are stripped from the formers. To ensure thorough drying and cooling, the gloves are gone through the cooling conveyor.

6.0 QUALITY CONTROL OF PRODUCT

BRIEF SUMMARY OF QUALITY CONTROL

6.1 ON-LINE QUALITY ASSURANCE INSPECTION

6.1.1 QA Lot Inspection

6.1.1.1 Every 2 hour, QA Inspectors shall randomly sample 125 pcs gloves from each production line (a batch). (Sampling is as per ISO 2859-1, G1 Inspection Level)

6.1.1.2 For each batch's samples, the following shall be performed:
i. physical dimension criteria
ii. visual inspection : all pieces
iii. watertight test : all pieces

6.1.1.3 Physical Dimension Criteria
-Physical dimension test involves checking of:
i. cuff, palm, finger thickness (1 piece)
ii. width (1 piece)
iii. length (5 pieces)
iv. weight (10 pieces)
-Report result for cuff, palm and finger thickness; and all individual results for length and width in the QA On Line Inspection Report.
-Weight of gloves shall be reported in gram as an average of all sample gloves.
-Acceptance criteria: AQL 4.0

6.1.1.4 Acceptance Criteria Visual and Watertight test
- QA inspector is responsible to carry out the visual and watertight tests.
- Gloves shall be inspected at the cuff and other areas of each sample for defects
- The samples shall be watertight tested by filling the gloves with 1000±50ml of water as per EN455 Part 1.
- For visual and watertight sampling plan and inspection level, refer to Table MGM-FTF-3B(II)

TABLE MGM-FTF-3B(II): SAMPLING PLAN, INSPECTION LEVEL & AQL FOR QUALITY ASSURANCE LOT INSPECTION

Visual and Water tight: Inspection Level G1

	Sample Size	Critical AQL	Defect 1.5	Major AQL	Defect 2.5	Minor AQL	Defect 4.0
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	2	3	3	4	5	6
3201-10000	80	3	4	5	6	7	8
10001-35000	125	5	6	7	8	10	11
35001-150000	200	7	8	10	11	14	15
150001-500000	315	10	11	14	15	21	22
500001+	500	14	15	21	22	21	22

	Sample Size	Critical AQL	Defect 2.5	Major AQL	Defect 2.5	Minor AQL	Defect 4.0
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	3	4	3	4	5	6
3201-10000	80	5	6	5	6	7	8
10001-35000	125	7	8	7	8	10	11
35001-150000	200	10	11	10	11	14	15
150001-500000	315	14	15	14	15	21	22
500001+	500	21	22	21	22	21	22

	Sample Size	Critical AQL	Defect 4.0	Major AQL	Defect 4.0	Minor AQL	Defect 6.5
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	5	6	5	6	7	8
3201-10000	80	7	8	7	8	10	11
10001-35000	125	10	11	10	11	14	15
35001-150000	200	14	15	14	15	21	22
150001-500000	315	21	22	21	22	21	22
500001+	500	21	22	21	22	21	22

6.2 PRE-SHIPMENT QUALITY ASSURANCE INSPECTION

6.2.1 Sampling Procedure

6.2.1.1 After gloves are packed into inner boxes and cartons, QA inspector shall draw random sample from each lot for inspection.

6.2.1.2 ISO2859-1, G1 Inspection Level is used to draw the required number of gloves from the sample.

6.2.1.3 The following shall be performed on the sample:
-visual inspection
-water tight test
-label marking and sealing
-quantity per packing unit

6.2.1.4 Criteria for above inspection shall be classified into Critical, Major and Minor defects. Refer attached sampling inspection table.
A subset of these samples, using ISO 2859-1, S2 Inspection Level, will be inspected for dimension and thickness, against AQL 4.0.

6.2.2 Acceptance Criteria

6.2.2.1 If the samples meet all the requirements of the inspection, the lot shall be identified with "PASS" and approved for shipping.

6.2.2.2 If the samples fail on visual but can be reworked, QA supervisor shall reject the lot back to Packing to sort / rework on the gloves. It will be identified by "REWORK" on the pallet stacking list.

6.2.2.3 If the samples fail on water tight test, the lot shall be downgraded to AQL 2.5, AQL 4.0 product which will be respectively recorded on the pallet stacking list.

See Sampling Table for Pre-shipment Inspection (Table MGM-FTF-3B(III)).

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 and 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

EN 455-2	: Medical Gloves for Single Use Part 2. Specification for Physical Properties.
Inspection Level	: Median value shall achieved minimum requirement
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 MGM-WI-14 Recall of Goods.

TABLE MGM-FTF-3B (III): SAMPLING TABLE FOR PRE-SHIPMENT & FINAL INSPECTION (BASED ON ISO 2859-1:1999)

Visual and Water tight: Inspection Level G1

	Sample Size	Critical AQL	Defect 1.5	Major AQL	Defect 2.5	Minor AQL	Defect 4.0
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	2	3	3	4	5	6
3201-10000	80	3	4	5	6	7	8
10001-35000	125	5	6	7	8	10	11
35001-150000	200	7	8	10	11	14	15
150001-500000	315	10	11	14	15	21	22
500001+	500	14	15	21	22	21	22

	Sample Size	Critical AQL	Defect 2.5	Major AQL	Defect 2.5	Minor AQL	Defect 4.0
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	3	4	3	4	5	6
3201-10000	80	5	6	5	6	7	8
10001-35000	125	7	8	7	8	10	11
35001-150000	200	10	11	10	11	14	15
150001-500000	315	14	15	14	15	21	22
500001+	500	21	22	21	22	21	22

	Sample Size	Critical AQL	Defect 4.0	Major AQL	Defect 4.0	Minor AQL	Defect 6.5
QTY (Pcs)	(pcs)	Acc	Rej	Acc	Rej	Acc	Rej
1201-3200	50	5	6	5	6	7	8
3201-10000	80	7	8	7	8	10	11
10001-35000	125	10	11	10	11	14	15
35001-150000	200	14	15	14	15	21	22
150001-500000	315	21	22	21	22	21	22
500001+	500	21	22	21	22	21	22

For Dimension, Thickness & Physical Properties: Inspection Level S2, AQL 4.0

Quantity (pieces)	Sample Size (pieces)	Dimension AQL 4.0		Thickness				Physical Properties			
				Palm AQL 4.0		Finger AQL 4.0		Tensile Strength AQL 4.0		Ultimate Elongation AQL 4.0	
		Acc	Rej	Acc	Rej	Acc	Rej	Acc	Rej	Acc	Rej
35,001 to 150,000	13	1	2	1	2	1	2	1	2	1	2
150,001 to 500,000	13	1	2	1	2	1	2	1	2	1	2
500,001 +	13	1	2	1	2	1	2	1	2	1	2