TECHNICAL FILE

Product : Powder Free Nitrile Examination Gloves, Polymer Coated, Non-Sterile.

File No. : TF 001/OLPYNF (3.5 g)

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5.0 APPENDICES

1.0 ADMINISTRATIVE DOCUMENTATION

1.1 NAME AND ADDRESS OF THE MANUFACTURING PLANT

The manufacturer of the product in this Technical File is

PERUSAHAAN GETAH ASAS SDN BHD (89707-V)

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1.2 PRODUCT DESCRIPTION

1.2.1 General Description

- Glove Type:
  Powder Free Nitrile Examination Gloves, Polymer Coated, Non-sterile

- Common Feature:
  Non-Sterile, Powder Free, Finger Textured Surface, Single Use, Bead Cuff, Ambidextrous, Polymer Coated, Nitrile Gloves

- Material:
  Nitrile Butadiene Rubber (NBR)

- Colour:
  Blue, White

- Sizes:
  Extra Small, Small, Medium, Large and Extra Large

- Shelf Life:
  3 Years

1.2.2 Indication for Use

A Patient Examination Glove is a disposable glove intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

1.3 Medical Device Classification

1.3.1 Classification Criteria

The European council has per Directive 93/42/ EEC of 14 June 1993 divided medical devices into four different classes (I, IIa, IIb, III), taking into consideration potential risk with the technical design, duration (transient, short term, long term) and exposure (invasive and non-invasive) into account.

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies per Section 1.1 Annex IX of Medical Device Directive. Since examination gloves are non-invasive medical devices, they are classified as Class I Medical Devices.

All invasive devices with respect to body orifices (other than those which are surgically invasive) which are not intended for connection to an active medical device, are in Class I, if they are intended for transient use. Since examination gloves are also invasive devices with respect to body orifices, they are classified as Class I Medical Devices.

In view of the low level of vulnerability associated with the use of class I devices, manufacturer of Class I medical devices can declare its conformity with the regulations.

As such we declare conformity with existing regulation as specified under Section 4.2, EC Declaration of Conformity.

1.3.2 Classification of Medical Device

The classification does follow the rules of the Official Journal of the European Communities No. L169 dated 12.07.1993.

It is a non-invasive device to be classified under Class I, coming under Rule 1, as a device intended to be used as a mechanical barrier.

It is an invasive devices with respect to body orifices (other than those which are surgically invasive), which are not intended for connection to an active medical device, to be classified under Class I, coming under Rule 5, as a device intended for transient use.

2.0 TECHNICAL AND PROCESS DOCUMENTATION

The Powder Free Nitrile examination gloves are manufactured in accordance to the standard requirements of EN 455 Part 1, 2, 3, and 4, and MDD Directive 93/42/EEC.

2.1 PRODUCT SPECIFICATION

For the purpose of the inspection, the gloves shall be sampled and inspected in accordance to ISO 2859. The inspection levels and Acceptable Quality Level (AQL) shall conform to the standard requirements of EN455.

2.1.1 Dimension

The Table below summaries the dimension and inspection requirements for Powder Free Nitrile Examination Glove:-

Dimension	Particular	Specification, mm	Inspection Level / AQL
Palm width	Extra Small Small Medium Large Extra Large	75 ± 5 mm 85 ± 5 mm 95 ± 5 mm 106 ± 5 mm 116 ± 5 mm	S2 / AQL 4.0
Length		Min. 240 mm	
Thickness (single wall)	Cuff (25mm from bead) Palm (center of palm) Finger (13mm from tip)	Min.0.04 mm Min.0.05 mm Min.0.07 mm	

2.1.2 Physical Properties

The gloves shall conform to the physical properties and inspection requirements specified in table below:-

Physical Property			Inspection Level / AQL
Force at Break (EN 455-2)	Throughout Shelf life	Min 6.0 N	N = 13 Median Value
	After Ageing (at 70 ± 2°C for 166 ± 2 hours) and within 12 months of manufacture	Min 6.0 N	

2.1.3 Powder Residue

The gloves shall meet powder residue requirement when tested in accordance to EN455-3 as per Table below:-

Specification	Inspection Level / AQL	Test Method
Max. 2 mg/glove	N = 5	EN455 Part 3, ISO 21171

2.1.4 Water-Tight Test

The gloves shall be water tight when tested in accordance to EN455-1 as per Table below:-

Specification	Inspection Level / AQL	Test Method
Freedom from holes	G1 / AQL 1.5	EN 455 Part 1

2.2 Visual Inspection (In-house method)

Gloves are sampled for Visual as per Sampling Plan and Criteria listed below:-

2.2.1 Critical Visual Defects (Sampling Plan: 0 Accept; 1 Reject)

Type of defects

- Embedded debris or metal
- Embedded insect

2.2.2 Major Visual Defects (Sampling Plan: G1 / AQL 2.5)

Type of defects

- Crack line due to hand mold
- Deformed Glove / bulging
- Dirt / Stain ($\geq$ 1.0 mm²)
- Discoloration / Yellowish (yellow patches / spots)
- Double Dipping
- Folded Finger (Inverted Fingers)
- Beading – Incomplete / No / Residue / Blister / Torn Bead
- Large Lump or coagulum ($\geq$ 2.0 mm²)
- Mixed Sizes / Type
- Excessive Powder / Powder Mark
- Rolled Cuff
- Sticky (on the outside exceeding 5 mm in length)
- Thin Spot / Thin Streak
- Wrong Orientation (unturned)
- Wet Look
- Tacky (sticky wholly, partially or any area inside the gloves $\geq$ 5mm in length)

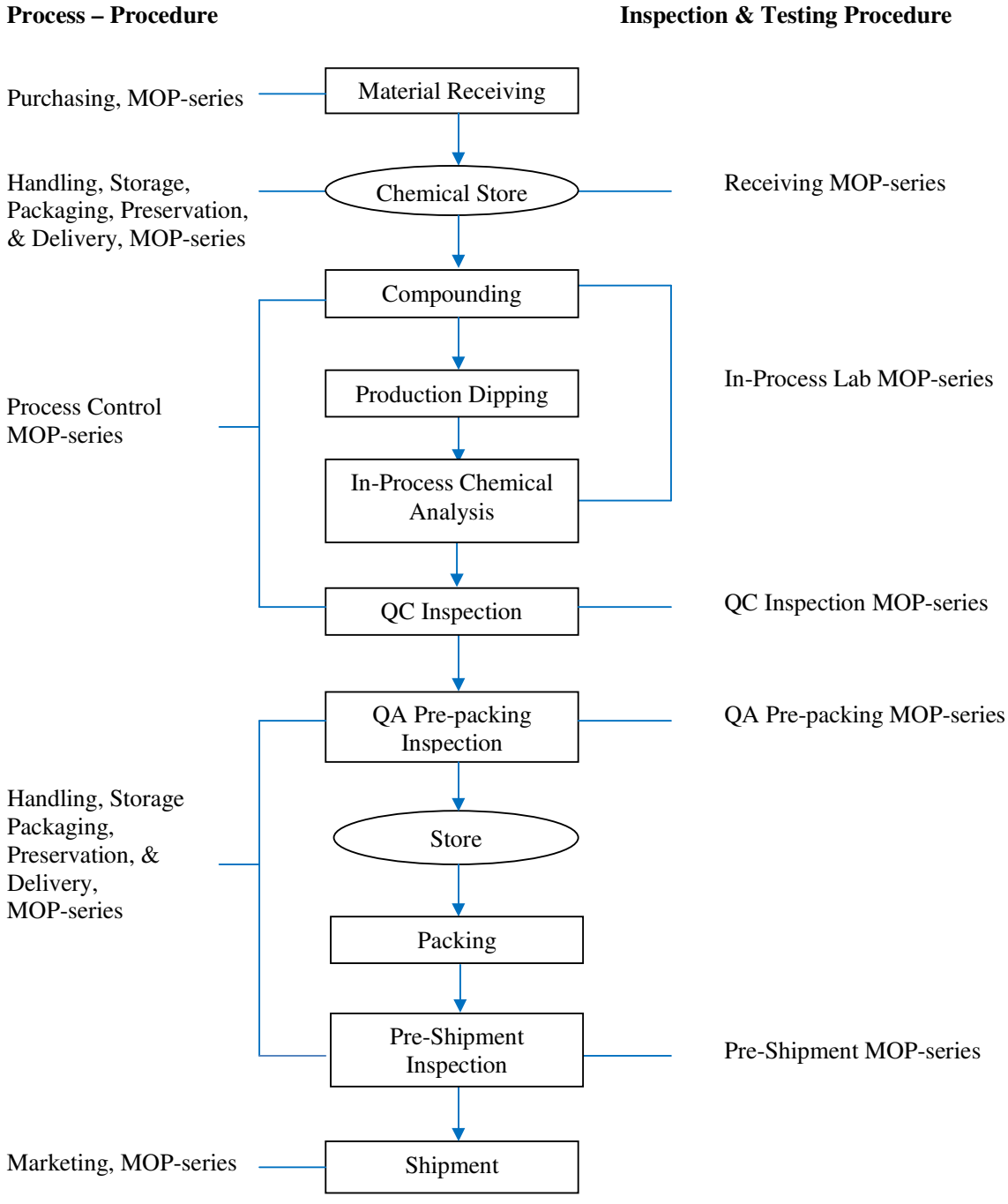
2.2.3 Minor Visual Defects (Sampling plan: G1 / AQL 4.0)

Type of defects

- Black Spot / Dirt / Stain Mark (< 1.0 mm^2)
- Micro Lumps / Coagulum (< 2 mm^2)
- Poor Beading
- Sticky (outside < 5 mm in length)
- Tacky (< 5 mm in length)

2.3 MANUFACTURING PROCESS AND QUALITY ASSURANCE PLAN

2.3.1 Manufacturing Flow Chart of Powder Free Nitrile Gloves



2.3.2 Quality Assurance Plan

2.3.2.1 Material Receiving

2.3.2.1.1 Materials are received and checked against the Purchase Order.

2.3.2.1.2 Supplier is required to present Certificate of Analysis or its equivalent for each shipment of chemicals and latex.

2.3.2.2 Incoming Material Inspection

2.3.2.2.1 Incoming materials that has effect on subsequent product realization, or the final product, are subjected to incoming inspection. The products will be placed in "Quarantine Area" for this purpose.

2.3.2.2.2 Incoming materials that meet In-house specifications are pasted with "Passed" Sticker.

2.3.2.2.3 Non-conforming products will be identified, segregated, and reviewed in accordance with Control of Non-Conforming Product Procedure.

2.3.2.2.4 Rejected materials will be pasted with "Reject" sticker, and returned to supplier.

2.3.2.2.5 Rejected materials will be quarantined at designated area while pending return to supplier.

2.3.2.3 Raw Material Milling and Compounding

2.3.2.3.1 Accepted materials with "Passed" Sticker are used for milling process.

2.3.2.3.2 All necessary compounding chemicals are milled as per compounding documentation.

2.3.2.3.3 The milled chemicals are tested and analyzed by laboratory personnel to ensure conformance to specification.

2.3.2.3.4 Milled chemical that passed laboratory analysis will be released for used in Compounding Process.

2.3.2.3.5 Milled chemical failed laboratory analysis shall be quarantine, re-milled, and retest for compliance.

2.3.2.3.6 The latex compounds are then analyzed by laboratory personnel according to specification requirements.

2.3.2.3.7 Latex compounds that conform to In-house specification will be released for used in production.

2.3.2.3.8 Latex compounds that failed laboratory analysis shall be quarantine, and reviewed in accordance with Control of Non-Conforming Product Procedure.

2.3.2.4 Production QC On-line Inspection

2.3.2.4.1 Each bin of glove is identified with Travel Card.

2.3.2.4.2 Gloves are sampled and inspected in accordance to ISO 2859 Table I and II-A, and specification requirements.

2.3.2.4.3 One Lot constitute of 6 bins shall be tested as detailed below:-

Characteristic	Inspection Level	AQL
Pin-hole (Watertight)	S4	1.5
Visual Critical	0 Accept; 1 Reject	NA
Visual Major	S4	2.5
Visual Minor	S4	4.0
Dimension and Thickness	S2	1.5

Note: Three (3) pieces sample per machine per week are tested for Unaged Physical Property Test. The samples are drawn from all machines sharing same batch of compound. This is for monitoring purposes as history records show gloves physical properties were consistently meeting requirement and specification.

2.3.2.3.4 Bins passed above-mentioned inspection are marked as AQL 1.5 on the Travel Card.

2.3.2.3.5 Bins failed above-mentioned inspection will be segregated, and quarantined in specified area at Store.

2.3.2.3.6 Passed AQL 1.5 bins will be sent to QA for Pre-packing Inspection.

2.3.2.5 Pre-Packing QA Inspection

2.3.2.5.1 Six (6) consecutive bins of gloves will be grouped together as one Lot for QA Inspection.

2.3.2.5.2 Gloves are randomly sampled by QA Pre-packing in accordance to ISO 2859, and inspected per specification requirements.

2.3.2.5.3 The inspection level and Acceptable Quality Level (AQL) shall conform to requirement specified below:-

Characteristic	Inspection Level	AQL
Pin-hole (Watertight)	S4	1.5
Visual Critical	0 Accept; 1 Reject	NA
Visual Major	S4	2.5
Visual Minor	S4	4.0

2.3.2.5.4 Gloves meet stipulated AQL level as specific above will be released for Packing.

2.3.2.5.5 Failed gloves shall be segregated and quarantined in specified area at Store.

2.3.2.6 Finished Goods Pre-shipment Inspection

Pre-shipment QA is performed on palletized packed gloves.

2.3.2.6.1 Gloves are randomly sampled in accordance to ISO 2859 Table I and II-A.

2.3.2.6.2 Overall inspection shall be conducted on palletized packed gloves per Size of each shipment.

2.3.2.6.3 The inspection level and Acceptable Quality Level (AQL) shall conform to requirement specified below:-

Characteristic	Inspection Level	AQL
Pin-hole (Watertight)	G1	1.5
Dimension and Thickness	S2	4.0
Visual Critical	0 Accept; 1 Reject	NA
Visual Major	G1	2.5
Visual Minor	G1	4.0
Physical Properties (Force at Break-EN 455 Part 2)	N= 13 (Median Value)	NA

2.3.2.6.4 Overall inspection per size that passed Pre-shipment QA Inspection is delivered and transferred to Outgoing Store.

2.3.2.6.5 The pallets or overall packed gloves that have failed Pre-shipment QA Inspection shall be reworked by Packing Department.

2.3.2.6.6 Failed pallets shall be segregated and quarantined in specified area at Store.

3.0 SAFETY DOCUMENTATION

3.1 Risk Assessment

The Risk Assessment of Powder Free Nitrile Examination Gloves has been performed based on Guidelines in ISO 14971 standard requirements. A copy of the Risk Assessment is enclosed that covers the following contents:-

- Intended use/Intended purpose identify characteristics
- Identification of potential hazards
- Risk evaluation and acceptability
- Summary and Conclusion

3.2 Essential Requirement Checklist

The relevant essential requirements of Annex I of Medical Device Directive are applied as far as safety and performance of the device features are concerned.

Based on the evaluation, we herewith confirm that all applicable essential requirements are fulfilled. A copy of the Essential Requirement Checklist is enclosed with this Technical File.

3.3 List of Standard Applied

3.3.1 The following standards are applied with the use of the device, to fulfil the essential requirements of Medical Device Directive 93/42/EEC:-

- 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 980 Graphical symbols for use in the labelling of medical devices
- EN 1041 Information supplied by the manufacturer of medical devices.
- ISO 2859 Sampling procedures for inspection by attributes – Part 1: sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
- ISO 9001 Quality Management Systems - Requirements
- ISO 10993-1 Biological evaluation of medical devices – Part : 1 Evaluation and Testing
- ISO 10993-5 Biological evaluation of medical devices – Part : 5 Tests for in vitro cytotoxicity

- ISO 10993-10 — Biological evaluation of medical devices – Part : 10 Tests for irritation and sensitization
- ISO 13485 — Medical devices – Quality Management Systems – requirements for regulatory purposes.
- ISO 14971 — Medical devices - Application of risk management to medical devices.
- ISO 21171 — Medical gloves – Determination of removable surface Powder

3.4 Labelling Guides

The label shall bear the following particulars, per Annex I of Medical Device Directive 93/42/EEC:-

i. The name or trade name and address of the manufacturer. For devices imported into the Community , in view of their distribution in the Community, the label , or the outer packaging, or instruction for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community;

ii. The details strictly necessary to identify the device and the contents of the packaging especially for the users;

iii. Where appropriate, the batch code, preceded by the word 'LOT', or the serial number;

iv. Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;

v. Where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community;

vi. Any special storage and/or handling conditions;

vii. Any warnings and/or precautions to take;

viii. CE mark

4.0 QUALITY DOCUMENTATION

4.1 Device Test/Evaluation Data

Tests were conducted to ensure safety and effectiveness of the device is maintained as well as achieving protection requirement as defined in the Directive. The following test results are attached in this Technical File :-

i. Skin Irritation Test
ii. Dermal Sensitization Test
iii. Cytotoxicity Test

4.2 EC Declaration of Conformity

We do hereby state that below-mentioned product, as described under the Technical Files,

i) Powder Free Nitrile Examination Glove, Non-Sterile

Do conform to Council Directive 93/42/EEC, and its amendment Directive 2007/47/EC, concerning Medical Devices Class I.
A copy of EC Declaration is per attached.

4.3 REACH Compliance

REACH is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (EU).

We do hereby state that below-mentioned product, as described under the Technical Files,

i) Powder Free Nitrile Examination Glove, Non-Sterile

Do Not contain any chemicals listed in the Latest Candidate List of Substances of Very High Concern.
A copy of the REACH Declaration is enclosed in the Technical File.