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TECHNICAL INFORMATION SHEET



- 1) **Device Name:**
Supersoft Exam Gloves

- 2) **Description:**
Powder free Nitrile examination gloves, non-sterile, single use, chlorinated, textured fingers, ambidextrous, beaded cuff.

- 3) **Product Codes and Sizes:**

Product Code	Size	Inner barcode	Shipper barcode
41130	Small	9311059411305	19311059411302
41131	Medium	9311059411312	19311059411319
41132	Large	9311059411329	19311059411326
41133	XL	9311059411336	19311059411333

- 4) **Recommended Applications:**
Dental clinics, Hospital, Medical and Diagnostic, Veterinarian, Emergency services- ambulance, police, Laboratories, pharmaceutical and cosmetic industries, Aged care, Childcare centres.

- 5) **Materials:**
Nitrile Butadiene Rubber (NBR), Potassium Hydroxide, Sulphur, ZDBC, ZMBT, Zinc Oxide, Wingstay-L, Titanium Dioxide.

- 6) **Production Process:**
Former cleaning and washing, coagulant dipping, coagulant drying, nitrile dipping, nitrile drying oven, beading, leaching tank dip, main curing oven, cooling tank, chlorination tank, soak rinse tank, neutralizer, post leaching tank, blower, stripping, QC inspection, tumbling, packing, Pre-shipment inspection.

- 7) **Standards and Approvals:**
Gloves are tested to and comply with ISO 14971:2007, ASTM 6319 and EN455.
ARTG 216551

8) Dimensions:

Size	Weight P/pc +0.1/-0.1gm	Length -10mm	Thickness Finger single wall (min)	Thickness Palm single wall (min/max) mm	Thickness Cuff single wall (min/max) mm	Palm Width +/-5mm
Small	2.5gm	240mm	0.06mm	0.05/0.07mm	0.04/0.06mm	85mm
Medium	2.7gm	240mm	0.06mm	0.05/0.07mm	0.04/0.06mm	95mm
Large	3.0gm	240mm	0.06mm	0.05/0.07mm	0.04/0.06mm	105mm
XL	3.3gm	240mm	0.06mm	0.05/0.07mm	0.04/0.06mm	115mm

9) Physical Properties:

Description	Before Ageing	After Ageing
Elongation at break (%)	500 minimum	400 minimum
Tensile Strength (MPa)	14 minimum	14 minimum

Note: if Textured gloves then minimum requirements shall be 10% lower than those shown in table.

10) Colour:

Blue

11) Performance Requirements:

Gloves shall be sampled and inspected in accordance with ISO 2859-1. The inspection levels and acceptable quality limits (AQLs) shall conform to those listed in below table for the characteristics listed.

Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
Dimensions	S2	4.0	ASTM 6319
Physical Properties	S2	4.0	ASTM 6319
Watertightness	GI	1.5	ASTM 6319
Tensile Strength and Elongation at break (before and after accelerated aging)	S2	4.0	ASTM 6319
Visual Defects: Major Minor	GI	2.5 2.5	Manufacturers Practice
Packaging Defects: Regulatory Visual Critical (incl glove count)	GI GI S2	** 4.0 4.0	In house inspection

Notes:

*** indicates unacceptable at any level For Dimensions and Physical Properties a median of 13 test pieces used as per EN455-02-00*

12) Quality Control Inspection procedures:

- a) Shipment is placed in quarantine area separately from other gloves in warehouse as one lot
- b) Shipment is then sorted by sizes if shipment consists of more than one size.
- c) QC inspector records lot number(s) indicated on inner boxes and outer cases, sizes quantity of shipment, buyer, date, etc
- d) QC inspector selects at random samples according to ISO procedures for sampling, each lots of different sizes are handled separately
- e) Samples are sent for testing as per requirements
- f) Results of tests will be recorded and only those that meet acceptance criteria are released for dispatch. If shipment consists of more than one size, shipment will be released only when all lots of different sizes have passed.
- g) If a shipment is found to fail test requirements it will be rejected by QC inspector and not released for shipment.

13) Packing:

100 pieces will be packed into a dispenser box. The number contained in each dispenser box determined by physical count. 10 dispenser boxes are packed in 2 layers of 5 giving 10 dispenser boxes inside export quality shipper carton (outer).

14) Packaging specifications: For shipper carton

Size	Length mm	Width mm	Height mm	Gross weight kg
Small	310	250	232	3.4
Medium	310	250	232	3.6
Large	310	250	232	3.9
XL	310	250	232	4.2

15) Storage Conditions:

The gloves will maintain their properties when stored in dry conditions out of direct sunlight at between 10 to 30 degrees C.

16) Shelf Life:

The gloves shall have a shelf life of 3 years from the date of manufacture when stored in compliance with the above storage conditions.