

Datasheet for Nitrile examination gloves, powder Free, finger textured: (CVET(STA)-NCM-01FE)

General Info

Item number	Item name	Supplier item name	Supplier item No
(2)800119	Nitrile examination gloves Powder Free- finger textured	CVET(STA)-NCM-01FE Nitrile Glove Powder Free, X-Small, white	7022408
(2)800120	Nitrile examination gloves Powder Free- finger textured	CVET(STA)-NCM-01FE Nitrile Glove Powder Free, Small, white	7022409
(2)800121	Nitrile examination gloves Powder Free- finger textured	CVET(STA)-NCM-01FE Nitrile Glove Powder Free, Medium, white	7022410
(2)800122	Nitrile examination gloves Powder Free- finger textured	CVET(STA)-NCM-01FE Nitrile Glove Powder Free, Large, white	7022411
(2)800123	Nitrile examination gloves Powder Free- finger textured	CVET(STA)-NCM-01FE Nitrile Glove Powder Free, X-Large, white	7022412

Short product description	Nitrile Powder Free, Finger Textured surface, Offline Chlorination Gloves, Medical	
Supplier	SRI TRANG GLOVES (THAILAND) PUBLIC COMPANY LIMITED	
Related documents	SCT.PD.SP.05.036-200719 R.00	
Reference standards; ISO, EN...	Standard & No	Standard Text
	EN 455 Part 1, 2, 3 & 4 ASTM D6319 – 19 ISO 10993 ISO 15223-1 ISO 13485:2016	Medical gloves for single use Standard specification for Nitrile Examination gloves for Medical application Biological Evaluation of Medical devices Medical Devices – Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied – Part 1: General Requirements Medical devices – Quality management systems – Requirements for regulatory purposes.
Reference EU directives / regulations	Directive No. incl. changes	Name of Directive / regulation
	93/42/EEC 21CFR 820	Medical device directive Quality system regulation
Components (parts or accessories)	N/A	

Product

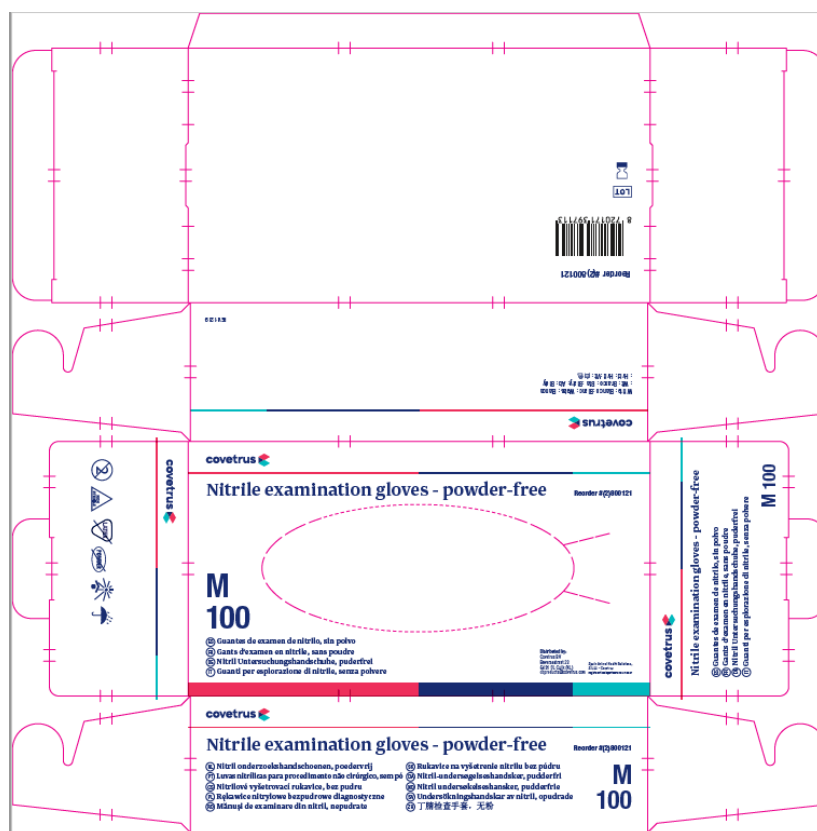
Product Details		Critical Major Minor	Covetrus Item No., size, component Specification – Tolerance Covetrus				
			Nitrile examination gloves				
			XS	S	M	L	XL
Length (mm)		Major	Med 240 mm.	Med 240 mm.	Med 240 mm.	Med 240 mm.	Med 240 mm.
Palm Width (mm)		Major	<= 80	80+/-10	95+/-10	110+/-10	>= 110
Weight (g/pc)		Major	2.6-3.1	2.5-3.3	3.1-3.8	3.5-4.3	4.0-4.9
Thickness	Finger (mm)	Major	Single wall Min 0.05 mm.				
	Palm (mm)	Major	Single wall Min 0.05 mm.				
Watertight Test		Major	Inspection level G I AQL 1.5				
Force at Break Before Aging (N)		Major	Med 6.5				
Force at Break (N) After Aging		Major	Med 6.0				
Tensile Strength Before Aging (Mpa)		Major	Min 14				
Tensile Strength After Aging (Mpa)		Major	Min 14				
Ultimate Elongation %		Major	Min 500				
Ultimate Elongation % After Aging		Major	Min 400				
Powder-free(mg)		Critical	≤2 mg per glove				
Protein Content(μ g/g)		Critical	≤50				

Product Details	Critical Major Minor	Covetrus Item No., size, component				
		Specification – Tolerance				
		Covetrus				
		Nitrile examination gloves				
		XS	S	M	L	XL
Chemical and Biological Test\ (Chemical permeation test, Chemical residue test, Cytostatic test, Cytotoxicity test, Food safe test, Irritation test, Powder residue test, Allergen (FIT Kit test), Protein t. extractable test, Sensitization test, Skin irritation test, Viral penetration test, Microbiology test)	Critical	Comply with 10993				
Visual defects	Critical	N/A				
Visual defects	Major	Inspection level G I AQL 1.5				
Visual defects	Minor	Inspection level G I AQL 4.0				
Environment of storage	Minor	Keep storage area cool, dry and dust free, avoid ventilation and storage close to photocopy equipment. Copper ions discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30 C will lead to accelerated aging and should be avoided under any circumstances. Long term storage in bulk can lead to pleats, stickiness and early aging of the glove and should be avoided.				
Environment of transportation	Minor	Should be transported in less than 80% relative humidity, non-corrosive gases and well-ventilated room, Avoid directly sunshine.				
Storage temperature	Major	0-30°C				
Shelf life	Major	3 years				
Sterilization	N/A	No <input checked="" type="checkbox"/> Yes <input type="checkbox"/> (Gamma);				
Single use only	N/A	No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>				
Quality plan inspection	N/A	Incoming, process, final and outgoing inspection.				
Inspection Level / Accepted Quality Level (AQL) (AQL)	N/A	Inspect of the product in accordance with Major AQL1.5 Minor 4.0				

Notice: Classification of visual defects ([Refer to attachment : STGT Criteria Defect](#))

Packaging

Drawing / Photo



Please fill in the form, or provide similar information in drawing and/or datasheet

Packaging Details	Packaging Component		
	Specification – Material - Tolerances		
	Unit	Inner box	Outer box
Amount	1 pcs	100 pcs	100X10 pcs
Marking	As per artwork	As per artwork	As per artwork
Barcode	As per artwork	As per artwork	As per artwork

Packaging Details	Packaging Component		
	Specification – Material - Tolerances		
	Unit	Inner box	Outer box
Text	As per artwork	As per artwork	As per artwork
Text colour	As per artwork	As per artwork	As per artwork
General	Package must not be damaged.		

Symbols



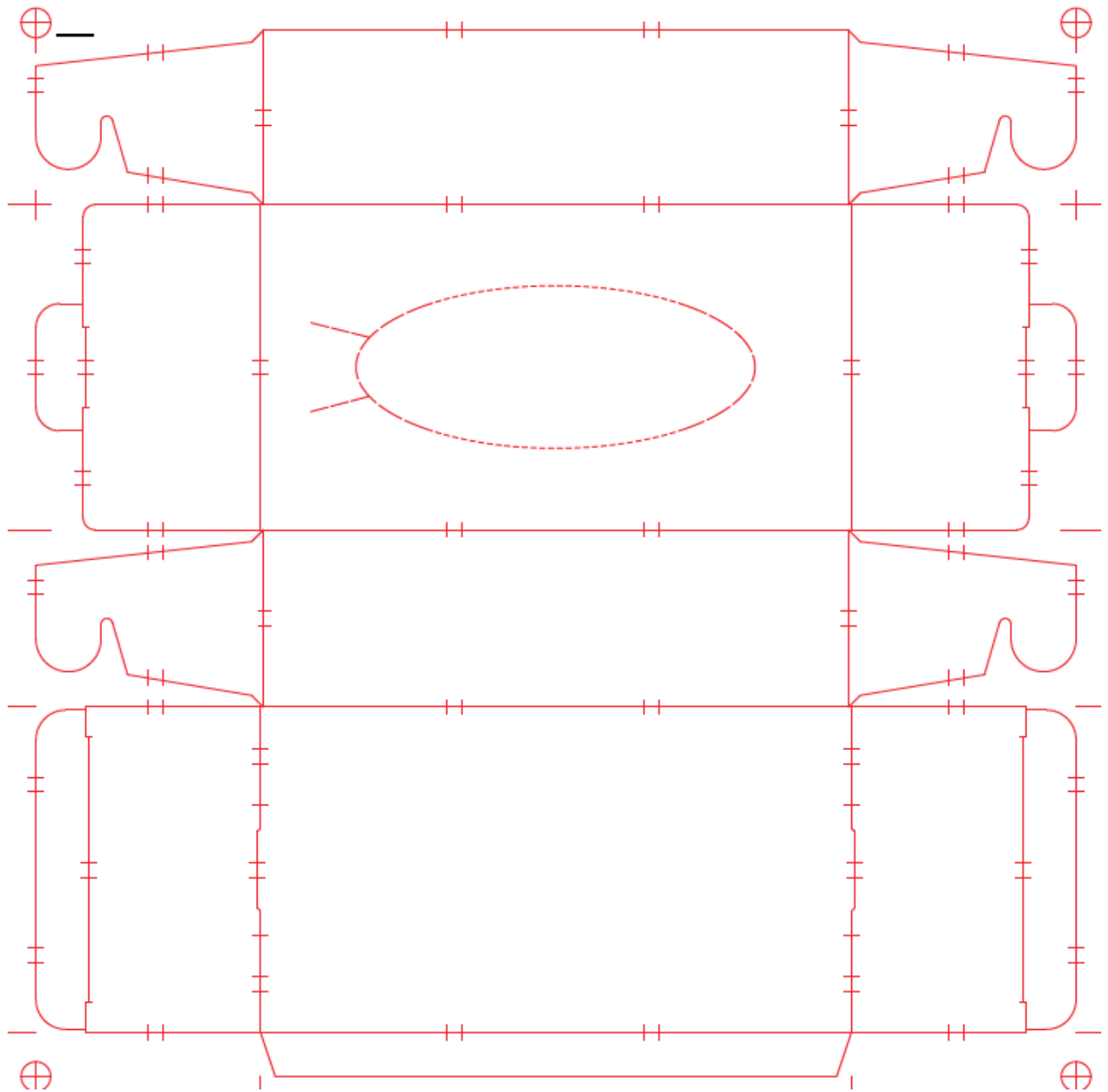
Other Requirements

- Packaging must be in accordance with:
- GB/T 6543: Single and double corrugated boxes for transport packages
- GB/T 6544: Corrugated fibreboard
- DIN 55468-1: Packaging materials - Corrugated board - Part 1: Requirements, testing
- DIN 55468-2: Packaging materials - Corrugated board - Part 2: Wet strength, requirements, testing
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DISPENSER:

Dispenser	Raw Material base	Duplex paper
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Layout



Carton:

Carton	Raw Material Base	KI150/CA125/ CA125 , B-Flute
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Layout

A = Liner paper, brown colour
M = Recycle paper, Brown colour
W = Liner paper, brown colour

Pair Pack Format Conventional Container:

Dimensions LxWxH in mm:	Packing per Unit:	Stacking per Unit:
Dispenser 200 x 110 x 60	Gloves flat in Dispenser	100 pcs (By weight)
Export Carton 310 x 225 x 210	Pack dispensers in Export Carton	10
20ft Container 5800x2330x2390	Carton 18 length 10 width 11 height	1,980 Cartons 1,980,000 Pcs.
40ft Container 11900x2330x2390	Carton 37 length 10 width 11 height	4,070 Cartons 4,070,000 Pcs.
40ft HC Container 11900x2330x2689	Carton 37 length 11 width 8 height + Carton 1 length 10 width 3 height + Carton 1 length 9 width 1 height + Carton 36 length 10 width 4 height	3,256+30+9+1,440 =4,735 Cartons 4,735,000 Pairs

Document History

Version	Date	Change
1		First Release

Preparation and Approval

Prepared by	Harvey xu	Date	2020-10-26
Approved by	Shelly Wei	Date	2020-10-26