YTY INDUSTRY (MANJUNG) SDN BHD			
Spec No. YTY1004/03 – 216 ASTM	**PRODUCT SPECIFICATION Henry Schein**		**Revision: DRAFT**
Product Information:			
Trade Name	Non-Sterile, Powder Free Nitrile Examination Gloves, Tested for use with Chemotherapy Drugs and Fentanyl Citrate.		
Brand Name	"Criterion Nitrile N100 Blue".		
Intended Use	A patient examination glove is a disposable device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner		
Product Conformance	ASTM D6319 Current Revision, ISO 13485 Current Revision, FDA QSR current Revision and Customer Requirement		
Material	Nitrile (Carboxylated Butadiene Acrylonitrile)		
Cuff Finishing	Beaded		
Color	Blue		
Type	Ambidextrous		
Coating	Coating (Process)-Donning Surface-Online Chlorinated		
Surface finish	Finger textured		
Product Shel Life	3 years (36 months).		
510K	K202536		
Product Specification:			
Dimension	Size	Palm Width (mm)	Length (mm)
	X-Small	75 ± 5mm	240min
	Small	85 ± 5mm	240min
	Medium	95 ± 5mm	240min
	Large	106 ± 5mm	240min
	Extra Large	115 ± 5mm	240min
Thickness	Single wall thickness (mm)		
		Specification	
	Cuff	0.05-0.08	
	Palm	0.08-0.15	
	Finger	0.09-0.17	
	Beading	0.5min	
		Un-aged	Aged
Physical Properties		Specification	Specification
	Tensile Strength (MPa)	14min	14min
	Ultimate Elongation (%)	500min	400min
	Modulus @ 300%	4.5 – 8.5 MPa	
Residual Powder	2.0 mg/glove maximum		
Quality Specification	Inspection Criteria		Sampling Plan/AQL
* AND – Accept No Defects	Dimension		S2 – AQL 4.0
	Physical Properties		S2 – AQL 4.0
	Water Tight Test		G1 – AQL 1.0 (Single Normal Sampling)
	Visual Inspection – Major		G1 – AQL 2.5
	Visual Inspection – Minor		G1 – AQL 4.0
	Residual Powder		n = 5 (average)
	Packaging Labeling		n = 5 (AND)
	Glove Physical Counting		n = 5 (AND)
Packaging Configuration and Labeling			
Packing	Packing - XS-L : 100 Gloves per Inner Dispenser (by weight); XL : 90 Gloves per Inner Dispenser (by weight) 10 Dispensers per Outer Carton		
Labeling	The dispensers and outer cartons shall have the following information/prints: Product description and Brand including size and net quantity of gloves. Name and Country of Origin of Manufacturer or Distributor. Symbol for single use and/or Single Use Only and Non-Sterile		
Lot Numbering System	Lot Numbering System - In house as per packing SOP YNXXXXXXXXX (E.g. : YN402910213) Y-YTY N- Nitrile		

	4 - Last digit of year (E.g. : 2024 = 4) 029 - Julian date (which refers to 10 days before committed ETD) 1 - Size (XS- 5, S- 3, M-2, L-1, XL-6) 0213 - System generated number Manufacturing and expiry date format to follow “YYYY-MM-DD”. .	
Authorized by: Vengatesh QA Sr. Manager		Code: **N48SYB** XS - 111-8533 S - 111-8535 M - 111-8536 L - 111-8537 XL - 111-8539 Glove weight for size M, 4.8g tolerance of +/-0.2g. (Glove weight is for monitoring purpose only)