

PRODUCT SPECIFICATION

Natural Rubber / Latex Examination Gloves

Product Description				
Size	Extra Small	Small	Medium	Large
Item#	9790954	9795137	9799020	9794477
Item #	9790511	9790512	9790513	9790514
Brand		DE Healthcare		
Color		Natural		
Intended Use		Patient Examination Gloves		
Product pictures		N/A		
Main Raw Material		NR Latex		
Sterility		Non-Sterile		
Design Shape/Form		Ambidextrous		
Surface Feature		Bees Textured		
Surface Treatment		Polymer Coated, Powdered / Powder free		
Scent		Unscented		
Other special feature		N/A		
Regulatory classification		Class 1		
Performance Requirements				
Dimension and Tolerance				
- Inspection Level - AQL		N=13 Median value must comply		
Palm Width (mm)	Extra Small	≤ 80		
	Small	80±10		
	Medium	95±10		
	Large	110±10		
	Extra Large	≥110		
Length (mm)		min. 240		
Thickness (mm)	Cuff	0.08 – 0.13		
	Palm	0.12 – 0.17		
	Finger	0.15 – 0.20		
Barrier Integrity				
- Inspection Level - AQL		G-1 1.5		
Physical Properties				
- Inspection Level - AQL - Before Ageing - After Ageing		N=13 Median value must comply Median ≥ 6.0N Median ≥ 6.0N		
Powder Free Residue (Powder Free Gloves)				
- Inspection Level - AQL		N=5 N/A		

• Requirements	≤ 2.0mg/gloves
Protein Content	
• Inspection Level	N=3
• AQL	N/A
• Requirements	≤50.00 µg/g
Powder Amount (Powdered Gloves)	
• Inspection Level	N/A
• AQL	N/A
• Requirements	N/A
Packaging and Marking	
• Packing Mode (for sterile and non-sterile)	100 pieces/box, 10 boxes/case
• Labeling Requirements (for sterile and non sterile)	Non-sterile
Packing Quantity (gloves, pcs)	100±2
Manufacturing Lot Number Format	NNN MMY (3 Digits Numbers/ 2 Digits Months / Year)
Manufacturer date format (OPTIONAL)	N/A
Special labelling (if applicable)	N/A
Material made of packages (if applicable)	N/A
Environmental Limitations	
Storage Conditions	Cool & Dry Environment
Shelf Life	3 Years
Regulatory Conformance	
Sampling and Inspection Standard (Reference)	ISO 2859-1
Product Standard (Reference)	EN 455 (Part 1 to 4)
Quality System	ISO 13485
Other Reference Document	N/A