

PRODUCT DATA SHEET

Description	
Product Name	Powder Free Latex Examination Gloves Aloe Vera
Product Description	Brand : HENRY SCHEIN GREEN ALOE VERA
	XS - 900-2871 S - 900-2872
	Item Code : M - 900-2873 L - 900-2874 XL - 900-2875
	Size : X-Small, Small, Medium, Large & X-Large
	Color : Green
Intended Use	Medical Activities
Main Raw Material	Natural Rubber Latex
Sterility	Non-Sterile
Design Shape/Form	Ambidextrous
Surface Feature	Textured at palm and finger
	Smooth at cuff
Surface Treatment	Chlorination for smooth donning (Inner surface)
Other Special Feature	N/A
Regulatory Classification	Class 1 Medical Device

Performance Requirement					
Dimension and Tolerance					
• Inspection Level (Sample Size)	N=13				
• Acceptance criteria	Median value for length and width must comply.				
• Palm Width	X-Small ≤80	Small 81-89	Medium 90 - 99	Large 100 - 109	X-Large 110 - 119
• Length (Median)	240 mm				
• Thickness (Palm)	0.11 - 0.17 mm				
• Thickness (Finger)	0.13 - 0.20 mm				
• Gloves Weight (Medium)	6.3 g				
Barrier					
• Inspection Level	G1				
• AQL	Free from holes	AQL 1.5			
	Visual - Major	AQL 2.5			
	Visual - Minor	AQL 4.0			

<u>Physical Properties</u>	
• Inspection Level (Sample Size)	N=13
• Acceptance criteria	Median value must comply.
• Before aging	Med ≥ 6N
• After aging	Med ≥ 6N

<u>Powder Residue (powder free gloves)</u>	
• Inspection Level	N=5
• Requirements	Max : 2.0mg/glove
<u>Protein Content</u>	
• Inspection Level	N=8
• Requirements	Max : 50µg/g
<u>Packaging and Marking</u>	
• Labeling requirements (for sterile and non sterile)	Boxes : Lot Number
	Cases : Lot Number and Case Number
• Packaging Quantity	100 gloves ± 2 gloves per box
	10 boxes per case
• Manufacturing Lot Number Format	hhhhijkk • hhhh - Last 4 digit of customer PO No. • i - Gloves Size. • jj - Month of container ship. • kk - Year of container ship.
<u>Environmental Limitations</u>	
• Storage Conditions	Dry cool condition (Avoid ozone)
• Shelf Life	3 years
<u>Regulatory Conformance</u>	
• Sampling and Inspection Standard (Reference)	ISO 2859
• Product Standard (Reference)	EN 455
• Quality System (Reference)	ISO 13485, ISO 9001
• Other Reference Document (if applicable)	Medical Device Regulation (EU) 2017/745

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