SPECIFICATION SHEET

Product Name			EPIC N Powder Free Nitrile Surgical Gloves, Accelerator Free	
Reorder Number			EP-13-xx	
Product Part Number			402xx.104721000	
Product Description				
Design and Feature			Hand specific, micro roughened surface, and beaded cuff	
Type			Powder free and Gamma-sterilized surgical gloves	
Material			Nitrile (Not made with Natural Rubber Latex)	
Colour			White	
Surface Treatment			Polymer coated	
Product Quality Requirement				
Dimension		Size	Palm Width (mm)	Length (mm)
		5.5	72 ± 4	Min. 278
		6.0	77 ± 5	Min. 280
		6.5	83 ± 5	Min. 280
		7.0	89 ± 5	Min. 283
		7.5	95 ± 5	Min. 287
		8.0	102 ± 6	Min. 288
		8.5	108 ± 6	Min. 290
		9.0	114 ± 6	Min. 290
Single-wall Thickness (mm) *All sizes		Finger	0.16 ± 0.02	
		Palm	0.13 ± 0.02	
		Cuff	0.11 ± 0.01	
Powder Residue (mg/glove)			≤ 2	
Physical Properties	Standard	Parameters	Before Aging	After Aging
	EN 455	Force at break (N)	≥ 9	≥ 9
	ASTM	Tensile Strength (MPa)	Min. 17	Min. 12
		Ultimate Elongation (%)	Min. 650	Min. 490
		Stress at 500% (MPa)	Max. 7.0	N/A
Shelf Life (upon manufacturing date)			3 years	
Glove Cuff Printing			No marking	
Packing Configuration			1 pair of gloves per inner wrapper, 1 inner wrapper per pouch, 50 pouches per dispenser, 6 dispensers per carton (Long Pack)	
Pre - shipment Inspection *Single-Normal Sampling Plan	Parameters/Standard		EN 455	ASTM
	Dimension		N=13, Median	S-2, AQL 4.0
	Physical Properties		N=13, Median	S-2, AQL 4.0
	1000ml Water Leak		G-I, AQL 0.65	G-I, AQL 0.65
	Powder Residue		N=5	N=5
	Visual Inspection (Major Defects)		G-I, AQL 1.5	G-I, AQL 1.5
	Visual Inspection (Minor Defects)		G-I, AQL 2.5	G-I, AQL 2.5
Product Conformance				
Medical Device			EU Compliance: MDR (EU) 2017/745 (CE Class IIa)	EN 455 Part 1,2,3,4
			US Compliance	ASTM D3577
Personal Protective Equipment			EU Compliance: PPE Regulation EU 2016/425 (PPE Cat.III)	EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018 Type B, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016 & ISO 16604:2004
			UK Compliance: Regulation 2016/425 on personal protective equipment, as amended to apply in GB	
US FDA			510K: K000971 MDL: D036529	
Glove Marking			Medical Device: CE 2797 PPE: CE 2797 & UKCA 0086	
Quality Assurance & Environment Management System				
• MDSAP ISO 13485:2016 Quality Management System • ISO 9001:2015 Quality Management System • EN ISO 13485:2016 Quality Management System – Regulatory Purpose • ISO 14001:2015 Environmental Management System				

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