

DHD with Moisturizer

Product : Powder Free Sterile Latex Dual Surgical Gloves

Product Description

Description	Under glove	Over glove
Material	Natural Rubber Latex	Natural Rubber Latex
Colour	Green	White to Pale Yellow
Shape	Anatomic	Anatomic
Cuff	Beaded	Beaded
External Surface	Antitack Polymer Treated	Antitack Polymer Treated
Internal Surface	Polymer Coated with Moisturizer	Polymer Coated
Shelf Life	3 Years	
Sterilization	EO/ Gamma	
Basic UDI DI	806363LSGFM4	

Product Classification

Medical Device : Class IIa, Rule 06
 Notify Body No. : 2460
 Regulatory Authority : DNV Product Assurance AS Norway.
 PPE Device : Category III (Module D)
 Notify Body No. : 0598
 Regulatory Authority : SGS Fimko Oy, Finland

Product Compliance

- ✓ EN 455 Parts 1,2,3 & 4
- ✓ ASTM D 3577, IS 13422, ISO 10282
- ✓ EN ISO 374 Parts 1,2,4 & 5, EN 16523, EN ISO 21420
- ✓ EN ISO 15223-1, EN 1041
- ✓ EN 556-1, EN ISO 11135, EN ISO 11137-1, EN ISO 11737-1 & 2, EN ISO 11138-2
- ✓ EN ISO 10993 Parts 1,5,7,10,11 & 23
- ✓ ISO 9001, ISO 14001, ISO 13485, EN ISO 14971

Product Packaging

➔ 4 boxes x 25 units / 200 units per Carton

Product Safety

Freedom from Holes : Inspection Level 1, AQL 0.65
 Visual Major Defects : Inspection Level 1, AQL 1.5
 Visual Minor Defects : Inspection Level1, AQL 2.5
 Protein Content : < 50 µg/dm²
 Powder Amount : <2 mg/glove

Physical Dimension (Underglove & Overglove)

Size	Minimum Length (mm)		Palm Width (mm)		Weight/pair (g)
	EN 455-2	Kanam	EN 455-2	Kanam	
5.5	250	270	72±4	74 - 75	15.5 – 16.0
6.0	260	280	77±5	81 - 82	16.5 – 17.0
6.5	260	280	83±5	84 - 85	18.0 – 18.5
7.0	270	280	89±5	91 - 92	19.8 – 20.4
7.5	270	285	95±5	98 - 99	21.0 – 21.5
8.0	270	285	102±6	103 - 104	22.0 - 22.5
8.5	280	285	108±6	108 - 109	23.0 – 23.5
9.0	280	285	114±6	113 - 114	24.5 – 25.0

Thickness (Underglove & Overglove)

Location	Minimum Thickness (mm)	
	ASTM D 3577	Kanam
Finger (13±3 mm from finger tip)	0.1	0.19
Palm (Center of the palm)	0.1	0.17
Cuff (25±5 mm from cuff edge)	0.1	0.14

Physical Properties (Underglove & Overglove)

Characteristics	Before Ageing		After Ageing (70±2°C for 166±2 h)	
	ASTM D 3577	Kanam	ASTM D 3577	Kanam
Tensile Strength (Mpa)	24 min	27 min	18 min	20 min
Ultimate Elongation (%)	750 min	900 min	560 min	800 min
Stress @ 500% Elongation (Mpa)	5.5 max	2.5 max	N/A	N/A
Force @ Break (N)	EN 455-2	Kanam	EN 455-2	Kanam
	9 min	12 min	9 min	10 min