

GOLDEN GLOVE



STERILE SURGICAL EXAMINATION GLOVES

POWDER-FREE & POWDERED

Standar Mutu

ASTM D63577
 Diproduksi sesuai QSR (GMP), ISO 9001
 Quality Management System dan ISO 13485
 Disterilisasi dengan Sterile EO

Ukuran

6.0, 6.5, 7.0, 7.5, 8.0

Spesifikasi Produk

Type : EO sterilized; Powdered atau Powder Free
 Material : Natural high quality latex
 Penyimpanan : Simpan di tempat kering dengan suhu dibawah 30°C
 Kadaluarsa : 5 tahun dari tanggal produksi
 Kemasan : 1 karton 8 box, 1 box 50 pairs/pouch



Nomor Izin Edar

Sterile Surgical Powder Kemenkes RI AKL 11603413809
 Sterile Surgical Powder Free Kemenkes RI AKL 11603912069



SECTION II : PERFORMANCE REQUIREMENTS (Sampling Plan - ISO 2859 Single Normal)

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D3577-09
		Median of 13 pieces		EN 455-2-2009+A:2011
2.2	Physical Properties	S2	4.0	ASTM D3577-09
		Median of 13 pieces		EN 455-2-2009+A:2011
2.3	Freedom from Holes	G1	1.5	In-house practice
2.4	Visual Defects : (i) Major Visual (ii) Minor Visual	G1	2.5	In-house practice
			4.0	
2.5	Packaging Defects : (i) Regulatory (ii) Visual (iii) Critical (incl. Gloves Counting)	G1	**	In-house practice
		G1	4.0	
		S2	4.0	
2.6	Powder Amount	N=2	N/A	ASTM D3577-09 ASTM D6124-06
2.7	Protein Content	N=3	N/A	ASTM D3577-09 ASTM D5712-05
2.8	Sterility	^	N/A	^US Pharmacopeia
2.9	Mix Size / Mix Glove / Mix Hand	Not	Allowed	

**Unacceptable at any level

Dimensi Produk

Dimensi	STANDARDS	
	GOLDEN GLOVE	ASTM D6319
Panjang (mm)	280 min	245 min (size 6) 265 min (size 8)
Lebar (mm)	- 6.0	76 ± 6
	- 6.5	83 ± 6
	- 7.0	89 ± 6
	- 7.5	95 ± 6
	- 8.0	102 ± 6
Tebal - Satu Lapis		
	- Ujung Jari - Telapak Tangan	0.10 min 0.10 min



PT. SUMBER ENERGY

Jl. Raya Manyar Tirtomoyo 52 Surabaya
 Mobile : 081 330 999 288, 082 122 181 081
 Tel : 031 - 594 7240
 Fax : 031 - 594 3697
 Website : www.sumberenergy.com
 Email : sales@sumberenergy.com