

SPECIFICATIONS
ROMED LATEX SURGICAL GLOVES PREPOWDERED, STERILE
REF: OPST060, OPST065, OPST070, OPST075, OPST080, OPST085, OPST090



Applicable harmonized standard: EN 455-1:2000, 2:2015, 3:2015, 4:2009, ISO 10282:2014
 Medical device conform MDD 93/42/EEC

APPEARANCE

- a. Creamy white colour
- b. Free from dust, dirt, oil stains and other foreign particles
- c. Anatomically shaped
- d. Micro rough surface in palm area
- e. Beaded cuff

FORMULATION

Raw material	Natural rubber latex (96.5 – 97%)
Curing agent	Sulphur
Accelerators	ZDEC – Zinc diethyldithiocarbamate ZDBC – Zinc dibutyldithiocarbamate
Activator	ZnO – Zinc oxide
Dispersing agent	Sodium salt
Stabilizer	Potassium hydroxide
Coagulant	Calcium nitrate
Powder	Inside USP absorbable corn starch powder
Thiuram urea not used	

PHYSICAL DIMENSION

Size	Length (mm, min.)	Width (mm)	Thickness (mm, min.)			Weight (gram, min.)
			Cuff	Palm	Finger	
6.0	280	77 ± 5	0.14	0.17	0.19	8.0
6.5		83 ± 5				8.5
7.0		89 ± 5				9.0
7.5		95 ± 5				9.5
8.0		102 ± 6				10.0
8.5		108 ± 6				11.6
9.0		114 ± 6				12.3

PHYSICAL PROPERTIES

Characteristics	Before Ageing	After Ageing
Tensile Strength	>24 MPa	>18 MPa
Force at break	>12.0 N	>9.0 N
Ultimate Elongation	>750%	>560%
Stress at 500% Elongation	<5.5 MPa	-

Freedom from holes	-	G-1 AQL 1.5
PH (approximate)	-	6-8
Total powder amount	-	< 15 mg/dm ²
Total protein content	-	<200 µg/g

Viral Penetration: ASTM F1671 compliant.

Sterilisation: Gamma Irradiation, valid for 5 years

Latex surgical gloves are phthalates, nitrosamine, NDMA and NDEA free.

PACKING

Per pair in a peel pouch, 50 pairs in an inner box, 8 inner boxes (=400 pairs) in an export carton.