

Isofield CR+

Sterile 400mm Powder-Free
Cleanroom Latex Gloves



PRODUCT INFO

GMP Grade A compatible
ISO Class 4 & 5 compatible
Sterile
100% natural latex
Powder-free
Natural colour
Elbow length 400mm (16")
Ambidextrous
Textured palm & fingers
Beaded cuff
Protein level less than 50µg/g
Double-donnable

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 Cleanroom

Physical properties comply with European medical glove standard EN455-2:2015

STERILIZATION

Gamma irradiation, Minimum 25 kGy

SHELF LIFE

Three (3) years from date of manufacture

STORAGE

Store in a dry, cool place (<40°C) away from direct sunlight. Do not expose open cartons to prolonged direct fluorescent light

PACKING

One pair per inner PE wallet,
One PE wallet per sealed PE pouch,
10 pouches per PE bag,
20 sealed PE bags per lined carton (200 pairs)



PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM*	MILS	TEST METHOD
Finger tip	0.20	7.87	EN455-2:2015
Palm	0.17	6.69	
Cuff	0.11	4.33	

* +/- 0.02mm

LENGTH	MIN	TYPICAL	TEST METHOD
From tip of middle finger to edge of cuff	390mm	400mm	EN ISO 21420 :2020

STRENGTH PROPERTIES	FORCE AT BREAK	TEST METHOD
Throughout shelf life	≥ 6.0 N	EN455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm ²)	3000	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm ²)	TEST METHOD
Fluoride (F)	0.0051	IEST-RP-CC005.4
Chloride (Cl)	1.967	
Nitrite (NO ₂)	ND	
Bromide (Br)	ND	
Nitrate (NO ₃)	0.278	
Phosphate (PO ₄)	ND	
Sulphate (SO ₄)	0.537	
Lithium (Li)	0.006	
Sodium (Na)	1.969	
Ammonium (NH ₄)	ND	
Potassium (K)	ND	
Calcium (Ca)	0.279	
Magnesium (Mg)	ND	
Zinc (Zn)	0.536	

* ND = Not Detected

PRODUCT CODE

REF 10040

SMALL	6.0-6.5	10040S
MEDIUM	7.0-7.5	10040M
LARGE	8.0- 8.5	10040L
XLARGE	9.0	10040XL