



# Isofield CR+

## 400mm (16") Sterile latex Cleanroom gloves

Last updated 22 Nov 2024

<b>PRODUCT CODE</b>	<b>REF</b>	<b>SMALL</b>	<b>6.0-6.5</b>	<b>10040S</b>	
	<b>10040</b>	<b>MEDIUM</b>	<b>7.0-7.5</b>	<b>10040M</b>	
		<b>LARGE</b>	<b>8.0-8.5</b>	<b>10040L</b>	
		<b>XLARGE</b>	<b>9.0</b>	<b>10040XL</b>	

### PRODUCT INFO

- Sterile latex Cleanroom gloves
- 400mm (16") elbow length
- Ambidextrous
- Natural colour
- Textured palm & fingers
- Beaded cuff
- Low endotoxin levels
- Gamma irradiation, minimum 25kGy
- Sterility Assurance Level 10<sup>-6</sup>
- Protein level less than 50µg/g
- Double donnable
- IPA resistant ink pouches

### CLEANROOM COMPATIBILITY

- GMP Grade A cleanroom
- GMP Grade B cleanroom
- ISO Class 4 cleanroom
- ISO Class 5 cleanroom
- Class 10 cleanroom
- Class 100 cleanroom

### 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 EN 455-2:2015

### APPLICATIONS

- Aseptic compounding and mixing
- Preparation of sterile emulsions
- Manufacture of sterile liquid and lyophilized vials
- Filtration, filling, stoppering and capping of vials

### STORAGE & SHELF LIFE

- Store in a dry, cool place (<40°C) away from direct sunlight
- Do not expose open cartons to prolonged direct fluorescent light
- Five (5) years from date of manufacture

### PACKAGING

- 1 pair per inner PE wallet,
- 1 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	EN 455-2:2015
Palm	0.17	6.69	EN 455-2:2015
Cuff	0.11	4.33	EN 455-2:2015

\* +/- 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	≥ 9.0 N	EN 455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	0.65 - Level 3 of 3	EN 374-2:2016

## CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm <sup>2</sup> )	< 1200	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm <sup>2</sup> )	TEST METHOD
Fluoride (F)	0.005	IEST-RP-CC005.4
Chloride (Cl)	0.750	IEST-RP-CC005.4
Nitrite (NO <sub>2</sub> )	0.042	IEST-RP-CC005.4
Bromide (Br)	0.043	IEST-RP-CC005.4
Nitrate (NO <sub>3</sub> )	0.410	IEST-RP-CC005.4
Phosphate (PO <sub>4</sub> )	0.044	IEST-RP-CC005.4
Sulphate (SO <sub>4</sub> )	0.120	IEST-RP-CC005.4
Lithium (Li)	0.006	IEST-RP-CC005.4
Sodium (Na)	0.040	IEST-RP-CC005.4
Ammonium (NH <sub>4</sub> )	0.110	IEST-RP-CC005.4
Potassium (K)	0.050	IEST-RP-CC005.4
Calcium (Ca)	0.510	IEST-RP-CC005.4
Magnesium (Mg)	0.010	IEST-RP-CC005.4
Zinc (Zn)	0.536	IEST-RP-CC005.4

\* ND = Not Detected

## TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Chemical innocuousness	EN ISO 21420:2020	Ensures the gloves do not adversely affect the health of the user. The materials present in the gloves must not release substances that are toxic
Sizing & dexterity	EN ISO 21420:2020 and EN ISO 374-2:2019	Determines sizing compliance and glove dexterity
Air leak & water leak	EN ISO 374-2:2019	Assesses the resistance of the glove to penetration
Chemical degradation	EN ISO 374-4:2019	Determines the resistance to degradation by dangerous chemicals
Chemical permeation	EN 16523-1:2015+A1:2018	Determines the resistance of protective glove materials to permeation by potentially hazardous non-gaseous chemicals
Viral penetration	EN 16604:2004	Assesses the resistance of glove materials to penetration by blood-borne pathogens
Endotoxin test	EN 455-3, USP	Specifies requirements for the evaluation of biological safety for gloves
Sterility validation test	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process
EU type certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product
UKCA type certificate	EN ISO 374-1:2016+A1:2018 Type B EN ISO 374-5:2016 EN ISO 374-4:2019	The applicable essential health and safety requirements of PPE Regulation (2016/425) as brought into UK law and amended as a Category III product



## LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	9.1 - 10.8kg	9.1 - 10.8kg
Carton size	W28 L32 H37cm	W28 L32 H37cm
Nett weight	6.3 - 8.0kg	6.3 - 8.0kg
Air freight pallet	Max height: 126cm Layers: 3 Cartons: 24	Max height: 126cm Layers: 3 Cartons: 36
Sea freight pallet	Max height: 163cm Layers: 4 Cartons: 32	Max height: 163cm Layers: 4 Cartons: 48

## DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)  
CERTIFICATE OF ANALYSIS (COA)  
CERTIFICATE OF IRRADIATION (COI)

View [sample](#) of COC, COA, COI



DECLARATION OF  
CONFORMITY (DOC)

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FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate,  
please [email us](#)

Country of origin: **Malaysia**  
HS Code: 4015199000

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