



# Isofield LS400

## 400mm (16") Non-sterile latex Cleanroom gloves

Last updated 15 Apr 2024

<b>PRODUCT CODE</b>	<b>REF</b>	<b>SMALL</b>	<b>10140S</b>	
	<b>10140</b>	<b>MEDIUM</b>	<b>10140M</b>	
		<b>LARGE</b>	<b>10140L</b>	
		<b>XLARGE</b>	<b>10140XL</b>	

### PRODUCT INFO

Non-sterile latex Cleanroom gloves  
 400mm (16") elbow length  
 Ambidextrous  
 Natural colour  
 Textured palm & fingers  
 Beaded cuff  
 Low endotoxin levels  
 Protein level less than 50µg/g  
 Double donnable

### CLEANROOM COMPATIBILITY

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

Handling of washed components  
 Preparation of solutions to be sterile-filtered  
 Loading and transporting 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  
  
 Three (3) years from date of manufacture

### PACKAGING

100 gloves per sealed inner PE bag,  
 1 inner PE bag per sealed outer PE bag,  
 10 outer bags per lined carton (1000 pieces)

## 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	≥ 6.0 N	EN 455-2:2015

FREEDOM FROM HOLES	PERFORMANCE	TEST METHOD
Acceptable Quality Level (AQL)	1.5 - Level 2 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
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	14.1 - 16.4kg	14.1 - 16.4kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	12.1 - 14.4kg	12.1 - 14.4kg
Air freight pallet	Max height: 139cm Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 Cartons: 40

## DOCUMENTATION



### CERTIFICATE OF CONFORMANCE (COC) CERTIFICATE OF ANALYSIS (COA)

View [sample](#) of COC, COA



### 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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