Isofield®
Protecting Life Science



Isofield LS400

400mm (16”) Non-Sterile Latex Cleanroom Gloves

Last updated **29 Oct 2026**

PRODUCT CODE	REF		
	10140	SMALL	10140 S
		MEDIUM	10140 M
		LARGE	10140 L
		XLARGE	10140 XL

CE 2797 AQL 1.5

PRODUCT INFO

Non-sterile latex Cleanroom gloves
400mm (16”) elbow length
Ambidextrous
Natural colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Food Safe. Complies limits established under Regulation (EU) No 10/2011
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

Five (5) years from date of manufacture

PACKAGING

100 pieces per inner bag,
1 inner bag per outer bag,
10 outer bags per carton (1000 pieces)

Packaging Materials

Inner Bag:
Low Density Polyethylene (LDPE)

Outer Bag & Carton Liner:
Low Density Polyethylene (LDPE)

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^2)	< 1200	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	0.005	IEST-RP-CC005.4
Chloride (Cl)	0.750	IEST-RP-CC005.4
Nitrite (NO_2)	0.042	IEST-RP-CC005.4
Bromide (Br)	0.043	IEST-RP-CC005.4
Nitrate (NO_3)	0.410	IEST-RP-CC005.4
Phosphate (PO_4)	0.044	IEST-RP-CC005.4
Sulphate (SO_4)	0.120	IEST-RP-CC005.4
Lithium (Li)	0.006	IEST-RP-CC005.4
Sodium (Na)	0.040	IEST-RP-CC005.4
Ammonium (NH_4)	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

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	< 10 min	ASTM D 6978-05 (2023)
Cyclophosphamide	Between 91 to 120	ASTM D 6978-05 (2023)
Doxorubicin Hydrocloride	> 240 min	ASTM D 6978-05 (2023)
Etoposide	> 240 min	ASTM D 6978-05 (2023)
Fluorouracil	> 240 min	ASTM D 6978-05 (2023)
Thiotepa	< 10 min	ASTM D 6978-05 (2023)
Methotrexate	> 240 min	ASTM D 6978-05 (2023)
Carboplatin	> 240 min	ASTM D 6978-05 (2023)

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	13.3 - 16.62 kg	13.3 - 16.62 kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	11.30 - 14.62 kg	11.30 - 14.62 kg
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)
CERTIFICATE OF PROCESSING (COP)

View sample of COC, COA, COP

DECLARATION OF CONFORMITY (DOC)

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FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate, please email us



Made in Malaysia
HS Code: 4015199000

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