Isofield®
Protecting Life Science



Isofield Stellar

400mm (16") Sterile Latex Cleanroom Gloves

Last updated **06 Nov 2026**

PRODUCT CODE

REF **10440**

SIZE 6.0	10440 60	SIZE 8.0	10440 80
SIZE 6.5	10440 65	SIZE 8.5	10440 85
SIZE 7.0	10440 70	SIZE 9.0	10440 90
SIZE 7.5	10440 75	SIZE 10.0	10440 100

CE 2797 UK CA 0086 AQL 0.65 STERILE R

PRODUCT INFO

Sterile latex Cleanroom gloves
400mm (16") elbow length
Hand-specific
Natural colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Gamma irradiation, minimum 25kGy
Sterility Assurance Level 10^{-6}
Food Safe. Complies limits established under Regulation (EU) No 10/2011
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 wallet,
1 inner wallet per pouch,
10 pouches per outer bag,
20 outer bags per carton (200 pairs)

Packaging Materials

Inner Wallet & Pouch:
High-density polyethylene (HDPE)

Outer Bag & Carton Liner:
Low-density polyethylene (LDPE)

PHYSICAL PROPERTIES

THICKNESS, SINGLE WALL	MM	MILS	TEST METHOD
Finger tip	0.21mm ±0.01	8.26 ± 0.39	EN 455-2:2015
Palm	0.19mm ±0.01	7.48 ± 0.39	EN 455-2:2015
Cuff	0.12 (minimum)	4.72 (minimum)	EN 455-2:2015

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^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
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

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)
Paclitaxel	> 240 min	ASTM D 6978-05 (2023)
ThioTERA	< 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	8.06 - 9.88kg	8.06 - 9.88kg
Carton size	W28 L32 H37cm	W28 L32 H37cm
Nett weight	5.26 - 7.08kg	5.26 - 7.08kg
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 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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