Isofield®
Protecting Life Science

Isofield Eclipse

400mm (16”) Sterile nitrile Cleanroom gloves

Last updated **04 Jun 2025**

PRODUCT CODE

REF **20440**

SIZE 6.0	2044060	SIZE 8.0	2044080
SIZE 6.5	2044065	SIZE 8.5	2044085
SIZE 7.0	2044070	SIZE 9.0	2044090
SIZE 7.5	2044075	SIZE 10.0	20440100

CE 2797 UK CA 0086 AQL 0.65 STERILE R

PRODUCT INFO

Sterile nitrile Cleanroom gloves
400mm (16”) elbow length
Hand-specific
White 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
Tested against a range of chemotherapy drugs
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

Aseptic assembly of filling equipment

Filtration, filling, stoppering and capping of vials

Staging and conveying of sterile primary packaging components

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	0.17	6.69	EN 455-2:2015
Palm	0.11	4.33	EN 455-2:2015
Cuff	0.09	3.54	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)	0.65 - Level 3 of 3	EN 374-2:2016

CLEANLINESS PROPERTIES

PARTICLES	TYPICAL PARTICLE COUNT	TEST METHOD
≥ 0.5µm (counts/cm^2)	< 950	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.344	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO_3)	0.388	IEST-RP-CC005.4
Phosphate (PO_4)	ND	IEST-RP-CC005.4
Sulphate (SO_4)	0.019	IEST-RP-CC005.4
Sodium (Na)	0.062	IEST-RP-CC005.4
Ammonium (NH_4)	0.011	IEST-RP-CC005.4
Potassium (K)	0.124	IEST-RP-CC005.4
Calcium (Ca)	0.313	IEST-RP-CC005.4
Magnesium (Mg)	ND	IEST-RP-CC005.4
Nitrite (NO_4)	ND	IEST-RP-CC005.4

** ND = Not Detected*

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME (MINS)	TEST METHOD
Carmustine	66 min	ASTM D6978-05
Cisplatin	> 240 min	ASTM D6978-05
Cyclophosphamide	> 240 min	ASTM D6978-05
Doxorubicin HCl	> 240 min	ASTM D6978-05
Etoposide	> 240 min	ASTM D6978-05
Fluorouracil	> 240 min	ASTM D6978-05
Methotrexate	> 240 min	ASTM D6978-05
Paclitaxel	> 240 min	ASTM D6978-05
Thiotepa	117 min	ASTM D6978-05

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
Permeation based on Chemotherapy Drugs	ASTM D6978-05 (2019)	Assesses the resistance of glove materials to permeation by potentially hazardous chemotherapy drugs
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	W80cm L120cm	W100 L120cm
Gross weight	7.6 - 8.3kg	7.6 - 8.3kg
Carton size	W28 L32 H30cm	W28 L32 H30cm
Nett weight	4.8 - 5.5kg	4.8 - 5.5kg
Air freight pallet	Max height: 135cm Layers: 4 Cartons: 32	Max height: 135cm Layers: 4 Cartons: 48
Sea freight pallet	Max height: 165cm Layers: 5 Cartons: 40	Max height: 165cm Layers: 5 Cartons: 60

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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