



Isofield CR+

400mm (16") Sterile latex
Cleanroom gloves

Last updated **12 Mar 2024**



PRODUCT CODE

REF

10040

SMALL
MEDIUM
LARGE
XLARGE

6.0-6.5
7.0-7.5
8.0-8.5
9.0

10040S
10040M
10040L
10040XL

CE 2797



EN ISO 374-5:2016
EN ISO 21420:2020
EN ISO 374-1:2018+
AS 2018
TYPE B
LATEX
RPT

UK
CA
0086
AQL 0.65
STERILE R

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^{-6}
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
Three (3) 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	≥ 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/cm²)	< 1200	IENT-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm²)	TEST METHOD
Fluoride (F)	0.005	IENT-RP-CC005.4
Chloride (Cl)	0.750	IENT-RP-CC005.4
Nitrite (NO ₂)	0.042	IENT-RP-CC005.4
Bromide (Br)	0.043	IENT-RP-CC005.4
Nitrate (NO ₃)	0.410	IENT-RP-CC005.4
Phosphate (PO ₄)	0.044	IENT-RP-CC005.4
Sulphate (SO ₄)	0.120	IENT-RP-CC005.4
Lithium (Li)	0.006	IENT-RP-CC005.4
Sodium (Na)	0.040	IENT-RP-CC005.4
Ammonium (NH ₄)	0.110	IENT-RP-CC005.4
Potassium (K)	0.050	IENT-RP-CC005.4
Calcium (Ca)	0.510	IENT-RP-CC005.4
Magnesium (Mg)	0.010	IENT-RP-CC005.4
Zinc (Zn)	0.536	IENT-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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