Isofield®
Protecting Life Science

Isofield CRN+

400mm (16”) Sterile nitrile Cleanroom gloves

Last updated **01 May 2024**

PRODUCT CODE

REF 20240

SMALL	6.0-6.5	20240S
MEDIUM	7.0-7.5	20240M
LARGE	8.0-8.5	20240L
XLARGE	9.0	20240XL

CE 2797 AQL 0.65 STERILE R

PRODUCT INFO

Sterile nitrile Cleanroom gloves
400mm (16”) elbow length
Ambidextrous
White colour
Textured palm & fingers
Beaded cuff
Low endotoxin levels
Gamma irradiation, minimum 25kGy
Sterility Assurance Level 10^{-6}
Tested against a range of chemotherapy drugs
Complies with EU food-grade regulation (EU) No 10/2011
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

Manufacture of sterile liquid and lyophilized vials

Filtration, filling, stoppering and capping of vials

Aseptic compounding and mixing

Preparation of sterile emulsions

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	0.17	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	390 mm	400 mm	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)	< 1800	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm^2)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.031	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO_3)	0.500	IEST-RP-CC005.4
Phosphate (PO_4)	0.062	IEST-RP-CC005.4
Sulphate (SO_4)	0.012	IEST-RP-CC005.4
Sodium (Na)	0.050	IEST-RP-CC005.4
Ammonium (NH_4)	0.020	IEST-RP-CC005.4
Potassium (K)	0.064	IEST-RP-CC005.4
Calcium (Ca)	0.432	IEST-RP-CC005.4
Magnesium (Mg)	ND	IEST-RP-CC005.4
Zinc (Zn)	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	W80 L120cm	W100 L120cm
Gross weight	7.46 - 8.48kg	7.46 - 8.48kg
Carton size	W28 L32 H30cm	W28 L32 H30cm
Nett weight	4.96 - 5.98kg	4.96 - 5.98kg
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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