



300mm (12") Sterile nitrile Cleanroom gloves

PRODUCT CODE	REF 20530	SIZE 6.0	2053060	SIZE 8.0	2053080	          
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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	0.16	6.30	EN 455-2:2015
Palm	0.14	5.51	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	290mm	300mm	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)	< 900	IEST-RP-CC005.4

EXTRACTABLES (ION)	TYPICAL VALUE (µg/cm ²)	TEST METHOD
Fluoride (F)	ND	IEST-RP-CC005.4
Chloride (Cl)	0.110	IEST-RP-CC005.4
Bromide (Br)	ND	IEST-RP-CC005.4
Nitrate (NO ₃)	0.318	IEST-RP-CC005.4
Phosphate (PO ₄)	ND	IEST-RP-CC005.4
Sulphate (SO ₄)	0.021	IEST-RP-CC005.4
Sodium (Na)	0.006	IEST-RP-CC005.4
Ammonium (NH ₄)	0.014	IEST-RP-CC005.4
Potassium (K)	0.034	IEST-RP-CC005.4
Calcium (Ca)	0.522	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	48 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	108 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	4.77 - 6.41kg	4.77 - 6.41kg
Carton size	W28 L32 H30cm	W28 L32 H30cm
Nett weight	2.27 - 3.91kg	2.27 - 3.91kg
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,
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Country of origin: **Malaysia**
HS Code: 4015199000

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EUROPE

ISOFIELD (IRELAND) LTD
70 Northumberland Road, Ballsbridge Dublin 4,
Ireland T +44 (0) 1638 6762 39

ASIA

ISOFIELD SDN BHD
6 Jalan Gudang 16/9, Seksyen 16, 40200, Shah Alam,
Selangor, Malaysia, T +603 5512 1709

CONTACT

www.isofield.com
info@isofield.com