

Isofield Vista Sleeve Cover

Sterile Cleanroom Sleeve Cover

PRODUCT INFO

Extra length sterile sleeve cover with thumb loops
55cm length for full arm coverage
Aseptically Folded
Class 1 for Cleanliness, static-dissipative & tested against chemotherapy
Microporous Polypropylene / Polyethylene
60gsm, Low-linting robust fabric

APPLICATIONS

Grade A & B and ISO Class 5 applications where fluid protection, viral barrier, low particle emissions required
Pharmaceutical product preparation
Cleanroom cleaning and preparation
Medical device manufacturing
Blending operations for biotechnologies
Handling of active materials
Maintenance of equipment and instruments

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

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

CLEANROOM COMPATIBILITY

GMP Grade A cleanroom
GMP Grade B cleanroom
ISO Class 4 cleanroom
ISO Class 5 cleanroom
Class 10 cleanroom
Class 100 cleanroom

PACKAGING

1 pair per inner bag,
10 pairs per outer bag,
10 outer bags per carton,
100 pairs per carton



PRODUCT CODE

REF 80771
SIZE UNIVERSAL

CE 2797  **STERILE IR**

MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight	g/m ²	ISO 9073-1-1989	±2	60
Machine Direction Strength	N/5cm		≥50	69
Machine Direction Elongation	%		≥100	109
Cross Direction Strength	N/5cm		≥25	43
Cross Direction Elongation	%		≥100	111
Hydrostatic Head	mmH ₂ O	ISO 811-1981	≥100	213
Air Permeability	l/m ² /S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	/	10 ⁷

HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION
≥ 0.3µm	743	less than 2,000
≥ 0.5µm	318	2,000 - 20,000

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	BREAKTHROUGH TIME	TEST METHOD
Carmustine	30 min	ASTM F739-20
Cisplatin	> 480 min	ASTM F739-20
Cyclophosphamide	> 480 min	ASTM F739-20
Doxorubicin HCl	> 480 min	ASTM F739-20
Etoposide	> 480 min	ASTM F739-20
Fluorouracil	> 480 min	ASTM F739-20
Methotrexate	> 480 min	ASTM F739-20
Paclitaxel	> 480 min	ASTM F739-20
Thiotepa	60 min	ASTM F739-20

*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory

TECHNICAL PROPERTIES

TEST REFERENCE	EXPLANATION	TEST RESULTS
EN 14325:2004 EN ISO 6530:2005	Repellency to chemicals	10% Sodium Hydroxide Level 3
		30% Sulphuric Acid Level 3
		O-Xylene Level 2
		Butan-1-ol Level 2
		70% Isopropyl Alcohol Level 2
		70% Ethanol Level 2
EN 14325:2004 EN ISO 6530:2005	Resistance to Penetration by chemicals	10% Sodium Hydroxide Level 3
		30% Sulphuric Acid Level 3
		O-Xylene Level 3
		Butan-1-ol Level 3
		70% Isopropyl Alcohol Level 3
		70% Ethanol Level 3
EN 14325:2004 EN ISO 9073-4:1997	Trapezoidal Tear Resistance	Machine Direction Class 2
		Cross Direction Class 2
EN 14325:2004 EN ISO 13934-1:2013	Tensile Strength	Machine Direction Class 1
		Cross Direction Class 2
EN ISO 13982- 2:2004 EN ISO 13982- 1:2004 (Type 5)	Inward Leakage of aerosols and fine particles into suits	Pass
	IL _{82/90}	0.765%
	IL _{8/10}	0.327%
EN 14325:2004 EN ISO 12947-2:2016	Abrasion Resistance	Class 2
EN 14325:2004 EN ISO 7854:1997, Method B	Flex Cracking Resistance	Class 6
EN 14325:2004 EN 863:1995	Puncture Resistance	Class 1
EN 14325:2004 [5.5]	Seam Strength	Class 2
EN 13034:2015 + A1:2009 ISO 17491-4:2008	Resistance to penetration by a spray of liquid (Spray Test)	Pass

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	6.53kg	6.53kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	4.58kg	4.58kg
Air freight pallet	Max height: 139cm Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 Cartons: 40

DOCUMENTATION



CERTIFICATE OF CONFORMANCE (COC)
CERTIFICATE OF ANALYSIS (COA)
CERTIFICATE OF PROCESSING (COP)

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FACTORY RELATED CERTIFICATIONS
To request ISO9001 Certificate,
please [email us](#)



Country of origin: **China**
HS Code: 6210109000

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