

# Isofield Horizon Sleeve Covers

## Non-Sterile Cleanroom Sleeve Covers

### PRODUCT INFO

Non-sterile sleeve covers with thumb loops

55cm length for full arm coverage

Class 1 for cleanliness, static-dissipative & tested against chemotherapy

Microporous Polypropylene / Polyethylene

60gsm, Low-linting robust fabric

### 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

### APPLICATIONS

Pharmaceutical product preparation

Cleanroom cleaning and preparation

Medical device manufacturing  
Blending operations for biotechnologies

Handling of active materials

Maintenance of equipment and instruments

### CLEANROOM COMPATIBILITY

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

### PACKAGING

10 pairs per inner bag,

10 outer bags,

100 pairs per carton

 Aseptic Fold

PRODUCT CODE

**REF 80770**  
UNIVERSAL SIZE



## MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight	g/m <sup>2</sup>	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 <sub>2</sub> O	ISO 811-1981	≥100	213
Air Permeability	l/m <sup>2</sup> /S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	/	10 <sup>7</sup>

## 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 <sub>82/90</sub>	0.765%
	IL <sub>8/10</sub>	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	5.67kg	5.67kg
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,  
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Made in Malaysia  
HS Code: 6210109000

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