

Isofield Vista Coverall with Hood

Sterile Cleanroom Coverall with Hood

PRODUCT INFO

Sterile Cleanroom coverall with Innovative Postbox hood design to ensure full face coverage

Taped zip flap, elasticated hood, waist, wrists, & ankles

Aseptically Folded

Class 1 for Cleanliness, static-dissipative & tested against Chemotherapy

Microporous Polypropylene / Polyethylene

Low-linting robust fabric

Excellent low-hazard liquid spray & fine particulates protection



QUALITY ASSURANCE

PPE Cat III, Type 5/6 certified

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

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

Aseptic filling & labelling

Medical device manufacturing

Blending operations for biotechnologies

Handling of active materials

Handling Chemotherapy

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 piece per sealed inner cleanroom bag,
1 inner bag per sealed outer bag,
20 outer bags per carton liner with twist tie,
20 pieces per carton (XS-XXL)
15 pieces per carton (3XL-4XL)

PRODUCT CODE

REF

80011

XSMALL	80011XS	XLARGE	80011XL
SMALL	80011S	2XLARGE	80011XXL
MEDIUM	80011M	3XLARGE	80011XXXL
LARGE	80011L	4XLARGE	80011XXXXL

CE 2797          **STERILE R**

Extra fabric around the neck area helps facilitate comfortable head movement



Innovative Postbox hood design to ensure full face coverage

Back elastic to prevent bellows effect



Thumbloop for easy donning



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	5.35 - 6.85kg	5.35 - 6.85kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	4.55 - 6.05kg	4.55 - 6.05kg
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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Country of origin: **Malaysia**
HS Code: 6210109000

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