Isofield Vista Coverall with Mandarin Collar

Sterile Cleanroom Coverall with Mandarin Collar



PRODUCT INFO

Two-layer mandarin collar provides secure fit at neck area

Zip flap with double-sided tape prevents ingress and egress of particles

Low-linting, anti-static fabric suitable for chemo handling

Elasticated thumb loops

Back elastic to prevent bellows effect

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 Chemotherapy

QUALITY ASSURANCE

PPE Cat III, Type 5/6 certifited

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 piece per inner bag,

1 inner bag per outer bag,

20 outer bags per carton (XS-2XL),

15 outer bags per carton (3XL-5XL)

Aseptic fold

PRODUCT CODE

REF 80821

XSMALL	80821 XS	2XLARGE	80821 2XL
SMALL	80821 S	3XLARGE	80821 3XL
MEDIUM	80821 M	4XLARGE	80821 4XL
LARGE	80821 L	5XLARGE	80821 5XL
XLARGE	80821 XL		

CE 2797 STERILE R

Last updated **27 Oct 2026**



Mandarin Collar

Back elastic to prevent bellows effect



Thumbloop for easy donning

MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic weight PP/PE film laminate	g/m^2	ISO 9073-1-1989	±2	60
Hydrostatic head	mmH_20	ISO 811-1981	≥100	213
Air permeability	$l/m^2/S$	GB/T5453	≥	2000
Surface resistivity	Ω / sq	ASTM D257	Static disspative	10^{10}

HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS	TEST METHOD
≥ 0.3µm	Conforms	Less than 2,000	1	IEST-RP-CC003.5
≥ 0.5µm	Conforms	2,000 - 20,000	1	IEST-RP-CC003.5
≥ 5.0µm	Conforms	20,000 - 200,000	1	IEST-RP-CC003.5

*Typical results

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	
	$IL_{82/90}$	0.544%	
	$IL_{8/10}$	0.233%	
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 (Type 6)	Resistance to penetration by a spray of liquid (Spray Test)	Pass	
In-house AQL 1.5	Test plan for major defect	Pass	
EN ISO11137 Part 2:2015	Sterility validation	SAL 10^{-6}	

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	4.86 - 6.28kg	4.86 - 6.28kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	4.08 - 5.50kg	4.08 - 5.50kg
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)

View sample of COC, COA, COP

FACTORY RELATED CERTIFICATIONS

To request ISO9001 Certificate, please email us



Country of Origin: China
HS Code: 6210109000

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EUROPE

ISOFIELD (IRELAND) LTD
Charter House, 5 Pembroke Row, Dublin 2
Dublin, D02 FW61, Ireland

ASIA

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

CONTACT

www.isofield.com
enquiries@isofield.com