

Isofield Alpha Kits

Sterile Cleanroom coverall with
mandarin collar, hood & overboots

PRODUCT INFO



MANDARIN COLLAR COVERALL

Sterile Cleanroom coverall with
mandarin style collar

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

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

Back elastic to prevent
bellows effect

Elasticated thumb loops



HOOD

Sterile postbox-style Cleanroom
hood

Latex-free enclosed elastic face
opening for comfortable fit

Extra-long yoke for added
protection



OVERBOOTS

Sterile Cleanroom overboots
Extra long — 50cm knee height
Two-ties for added security
Anti-slip PU sole

APPLICATIONS

Pharmaceutical product preparation

Cleanroom cleaning and preparation

Aseptic filling & labelling

Medical device manufacturing

Blending operations for
biotechnologies

Maintenance of equipment and
instruments

Handling chemotherapy in
hospital pharmacy

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

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 set (hood/coverall/boots)
per sealed inner bag,

1 inner bag per sealed outer bag,

40 sets per carton liner with
twist tie (XS-XXL),

35 sets per carton with
twist tie (3XL-4XL)

 Three items are aseptically folded

PRODUCT CODE

REF

80551

XSMALL	80551XS	XLARGE	80551XL
SMALL	80551S	XXLARGE	80551XXL
MEDIUM	80551M	3XLARGE	80551XXXL
LARGE	80551L	4XLARGE	80551XXXXL

CE 2797         



**Mandarin
Collar**



**Back elastic to prevent
bellows effect**



**Excellent forehead
coverage**

**Latex-free
enclosed elastic
face opening
at base for
comfortable fit**



**Two-ties
Overboots**

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 ₂ O	ISO 811-1981	≥100	213
Air permeability	l/m ² /S	GB/T5453	≥	2000
Surface resistivity	Ω / sq	ASTM D257	Static disspative	10 ¹⁰
Overboot slip resistance	Coefficient of Friction (COF)	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS	TEST METHOD
≥ 0.3µm	743*	Less than 2,000	1	IEST-RP-CC003.4
≥ 0.5µm	318*	2,000 - 20,000	1	IEST-RP-CC003.4
≥ 5.0µm	43*	20,000 - 200,000	1	IEST-RP-CC003.4

*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	13.09 - 16.54kg	13.09 - 16.54kg
Carton size	W38 L58 H47cm	W38 L58 H47cm
Nett weight	10.29 - 13.74kg	10.29 - 13.74kg
Air freight pallet	Max height: 109cm Layers: 2 Cartons: 8	Max height: 109cm Layers: 2 Cartons: 10
Sea freight pallet	Max height: 156cm Layers: 3 Cartons: 12	Max height: 156cm Layers: 3 Cartons: 15

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: **China**
HS Code: 6210109000

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