

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
Handling of active materials
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 a
twist tie (S-XXL),
35 sets per carton with a twist tie
(3XL-4XL)

 All three items are aseptically folded

PRODUCT CODE

REF

80551

XSMALL	80551XS	XLARGE	80551XL
SMALL	80551S	2XLARGE	80551XXL
MEDIUM	80551M	3XLARGE	80551XXXL
LARGE	80551L	4XLARGE	80551XXXXL

CE 2797              



**Mandarin
Collar**



**Back elastic to prevent
bellows effect**



Close up hood

**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

*Test carried out on coverall and hood. 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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