

# Isofield Alpha Kit

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 sole



## 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

## 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

## 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   STERILE IR



**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 <sup>2</sup>	ISO 9073-1-1989	±2	60
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 / sq	ASTM D257	Static disspative	10 <sup>10</sup>
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 <sub>82/90</sub>	0.544%
	IL <sub>8/10</sub>	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 <sup>-6</sup>

## 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)

View [sample](#) of COC, COA, COP



FACTORY RELATED CERTIFICATIONS  
To request ISO9001 Certificate,  
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Country of origin: **China**  
HS Code: 6210109000

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