

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

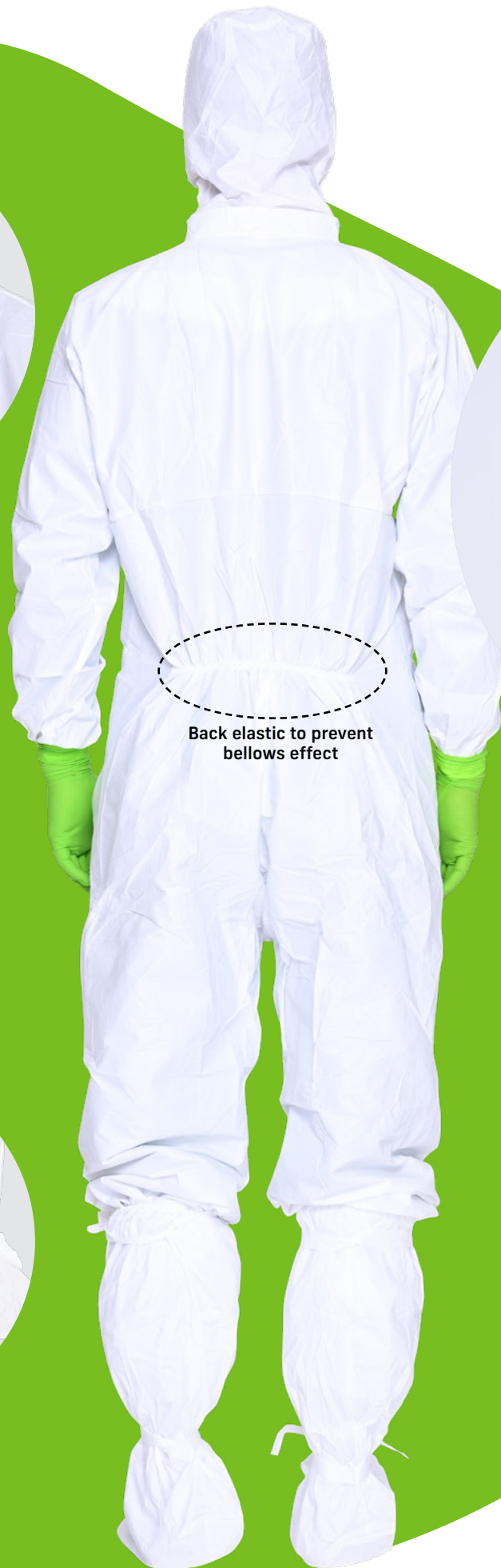
80551

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

CE 2797              



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

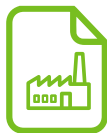
	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	13.09 - 16.54kg	13.09 - 16.54kg
Carton size	W38 L58 H47cm	W38 L58 H47cm
Nett weight	10.29 - 13.74kg	10.29 - 13.74kg
Air freight pallet	Max height: 109cm Layers: 2 Cartons: 8	Max height: 109cm Layers: 2 Cartons: 10
Sea freight 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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