



ALPHA & BETA STERILE KITS

Last updated: 12 Oct 2023



Isofield Alpha Kits

Sterile coverall with mandarin collar, hood and overboots



PRODUCT INFO

MANDARIN COLLAR COVERALL


GMP Grade A & B and ISO Class 4 & 5 cleanroom compatible
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

HOOD

Latex-free enclosed elastic face opening for comfortable fit
Extra-long yoke for added protection
Three panel hood design to minimize skin exposure

OVERBOOTS

Extra-long knee height
Two-ties for added security
Anti-slip PU sole

 All three items are aseptically folded

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system
Processed in a NEBB certified ISO Class 5 Cleanroom

APPLICATIONS

Pharmaceutical product preparation
Cleanroom cleaning and preparation
Aseptic filling and labelling
Medical device manufacturing
Blending operations for biotechnologies
Handling of active materials
Maintenance of equipment and instruments





MATERIAL PERFORMANCE PARAMETERS

DESCRIPTION	UNITS	METHOD	SPECIFICATION	TYPICAL
Basic Weight	g/m ²	ISO 9073-1-1989	±2	60
Machine Direction Strength	N/5cm		≥50	69
Machine Direction Elongation	%		≥100	109
Cross Direction Strength	N/5cm		≥25	43
Cross Direction Elongation	%		≥100	111
Hydrostatic Head	mmH ₂ O	ISO 811-1981	≥100	213
Air Permeability	l/m ² /S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	/	10 ⁻⁷
Overboots Slip Resistance	COF	ASTM D1894	≥0.5	0.6 (Static) 0.5 (Dynamic)

CLEANLINESS LEVELS	UNITS	METHOD	SPECIFICATION	TYPICAL
Particle Shedding	≥ 0.3µm (counts/min)	IEST-RP-CC003.4	2000	1000

ASTM F739-20 TEST METHOD

CHEMOTHERAPY DRUGS TESTED	MEAN BREAKTHROUGH TIME (MBT), MINUTES BREAKTHROUGH OF THE TEST CHEMICAL IS DEEMED TO HAVE OCCURRED WHEN THE PERMEATION RATE HAS REACHED 0.1 µg/cm ² /min*
Carmustine	30 mins
Cisplatin	> 480 mins
Cyclophosphamide	> 480 mins
Doxorubicin HCl	> 480 mins
Etoposide	> 480 mins
Fluorouracil	> 480 mins
Methotrexate	> 480 mins
Paclitaxel	> 480 mins
Thiotepa	60 mins

*Results achieved under controlled laboratory conditions, by accredited ISO 17025 third party testing laboratory

PACKAGING

1 set (hood/coverall/boots) per sealed inner bag
 1 inner bag per sealed outer bag
 40 outer bags per carton liner with twist tie (S-XXL)
 35 sets per carton (3XL)

SHELF LIFE

Three (3) years from date of manufacture

PACKAGING

Store in a cool, dry place (<40°C) away from direct sunlight

Do not expose opened cartons to prolonged direct fluorescent light

PRODUCT CODE	
REF	80551
SMALL	80551S
MEDIUM	80551M
LARGE	80551L
XLARGE	80551XL
XXLARGE	80551XXL
3XLARGE	80551XXXL
Note: Overboots and hood are universal size	

Isofield Beta Kits

Sterile coverall with mandarin collar, hood with integrated facemask and overboots



HOOD WITH
INTEGRATED
FACEMASK

OVERBOOTS

COVERALL
WITH
MANDARIN
COLLAR

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Back elastic to prevent bellows effect

HOOD WITH INTEGRATED FACEMASK

Integrated mask with ties for quick and easy donning
Latex-free enclosed elastic face opening for comfortable fit
Extra-long yoke for added protection
Three panel hood design to minimize skin exposure

OVERBOOTS

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Two-ties for added security
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 3XLARGE 80451XXXL

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Isofield Cleanroom Kits



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with mandarin
collar, hood and
overboots



BETA KITS
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with mandarin collar,
hood with integrated
facemask and
overboots