



# ALPHA & BETA STERILE KITS

Last updated: 26 Jan 2024



# Isofield Alpha Kits

Sterile coverall with mandarin collar, hood & 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 <sup>2</sup>	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 <sub>2</sub> O	ISO 811-1981	≥100	213
Air Permeability	l/m <sup>2</sup> /S	GB/T5453	≥	2000
Surface Resistivity	Ω	ISO 9073-1-1989	/	10 <sup>-7</sup>
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 <sup>2</sup> /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

**STORAGE**

Store in a cool, dry place (<40°C) away from direct sunlight  
 Do not expose opened cartons to prolonged direct fluorescent light

**COUNTRY OF ORIGIN: CHINA**

HS CODE: 6210109000

PRODUCT CODE	
<b>REF</b>	<b>80551</b>
SMALL	80551S
MEDIUM	80551M
LARGE	80551L
XLARGE	80551XL
XXLARGE	80551XXL
3XLARGE	80551XXXL
Note: Overboots & hoods are universal size	

# Isofield Beta Kits

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



HOOD WITH  
INTEGRATED  
FACEMASK

OVERBOOTS

COVERALL  
WITH  
MANDARIN  
COLLAR

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Low-linting, anti-static fabric suitable for chemo handling  
Elasticated thumb loops  
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

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

 All three items are aseptically folded

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**REF 80451**

SMALL 80451S  
MEDIUM 80451M  
LARGE 80451L  
XLARGE 80451XL  
XXLARGE 80451XXL  
3XLARGE 80451XXXL

Note: Overboots and hood are universal size

# Isofield Cleanroom Kits



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Sterile coverall  
with mandarin  
collar, hood &  
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## BETA KITS

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