

# Isofield Iota Kits

Steridon Cleanroom coverall with hood & overboots

## PRODUCT INFO



### COVERALL WITH HOOD

Sterile Cleanroom coverall with hood

Latex-free, enclosed & elasticated face, wrists & ankles

Ergo-fit design at back & shoulders allowing greater range of motion

Colour coded left & right inner tabs to facilitate ease of donning

Removable external tabs at zipper to ensure sterile field maintained

Validated for sterility by X-Ray

Sterility Assurance Level (SAL) 10<sup>-6</sup>

### OVERBOOTS

Extra long — 50cm knee height

Two ties for added security

Anti-slip PU sole



## QUALITY ASSURANCE

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 (steridon coverall/overboots) per sealed inner bag,

1 inner bag per sealed outer bag,

40 outer bags per carton liner with twist tie (XXS-XXL),

35 outer bags per carton liner with twist tie (3XL-5XL)

 Both items are aseptically folded

## APPLICATIONS

Applications where fluid protection, viral barrier, low particle emissions required

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

PRODUCT CODE

REF  
**80341**

XXSMALL	80341XXS	XLARGE	80341XL
XSMALL	80341XS	XXLARGE	80341XXL
SMALL	80341S	3XLARGE	80341XXXL
MEDIUM	80341M	4XLARGE	80341XXXXL
LARGE	80341L	5XLARGE	80341XXXXXL



Extra fabric around the neck area helps facilitate comfortable head movement

Ergo-fit design at back and shoulders to allow greater range of motion

Extra height 50cm



## BARRIER TEST/PERFORMANCE

BARRIER TEST/PERFORMANCE	TEST METHOD	TYPICAL VALUES
Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities /clothing for protection against contact with blood and body fluids-test Method using synthetic blood	ANSI/AAMI PB70 ISO 16603:2004 ASTM F1670	Level 4 Class 6
Viral penetration test (liquid challenge : bacteriophage Phi-X174)	ASTM F1671 ISO 16604:2004	Pass Class 4
Material resistance to wet bacterial Penetration	ISO 22610	Class 6
Resistance to penetration by biologically contaminated aerosols	ISO 22611	Class 3
Resistance to dry microbial penetration	ISO 22612	Class 3
Standard test method for permeation of liquids and gases through protective clothing materials under conditions of continuous contact	ASTM F739	See results on page 4
	ASTM D 6978-05	See results on page 4

## STERILITY ASSURANCE

NORM	TEST REFERENCE	EXPLANATION
Sterility validation	EN ISO 11137 Part 2:2015	Specifies requirements for the development, validation and routine control of a radiation sterilization process

## PHYSICAL PROPERTIES

PHYSICAL PROPERTIES	TEST METHOD	TYPICAL VALUES
Basis weight	ASTM D3776	52g/m <sup>2</sup>
Dry mullen burst strength	TAPPI T403 om-02	2100g/cm <sup>2</sup>
Tensile strength	ASTM D5034 (Grab CD)	7500g ( 16.5 lbf)
	ASTM D5034 (Grab MD)	11000g ( 24.5 lbf)
Trapezoid tear MD	ASTM D5733-95	2400g
Hydrostatic head with screen	AATCC 127	200cm
Wet peel CD (inner/outer)	ASTM F904-98	50/100g/2 in
Moisture vapor transmission rate (MVTR)	ASTM E96 Procedure D	1400g/m <sup>2</sup> /day
Static decay MD/CD	WSP 40.2	0.5/0.5 seconds
Slip resistance	ASTM D1894	0.6 (Static) 0.5 (Dynamic)

## PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	TEST METHOD	AVERAGE BREAKTHROUGH DETECTION TIME
Blenoxane	ASTM D 6978-05	> 240 mins
Cisplatin	ASTM D 6978-05	> 240 mins
Cytarabine	ASTM D 6978-05	> 240 mins
Dacarbazine	ASTM D 6978-05	> 240 mins
Ellence	ASTM D 6978-05	> 240 mins
Fludarabine	ASTM D 6978-05	> 240 mins
Gemcitabine	ASTM D 6978-05	> 240 mins
Idarubicin	ASTM D 6978-05	> 240 mins
Ifosfamide	ASTM D 6978-05	> 240 mins
Irinotecan	ASTM D 6978-05	> 240 mins
Mechlorethamine HCL	ASTM D 6978-05	> 240 mins
Melphalan	ASTM D 6978-05	> 240 mins
Methotrexate	ASTM D 6978-05	> 240 mins
Mitomycin C	ASTM D 6978-05	> 240 mins
Mitoxantrone	ASTM D 6978-05	> 240 mins
Vincristine Sulfate	ASTM D 6978-05	> 240 mins

CHEMOTHERAPY DRUGS	TEST METHOD	AVERAGE BREAKTHROUGH DETECTION TIME
Cyclophosphamide	ASTM F739-20	> 480 mins
Doxorubicin HCl	ASTM F739-20	> 480 mins
Etoposide	ASTM F739-20	> 480 mins
Fluorouracil	ASTM F739-20	> 480 mins
Paclitaxel	ASTM F739-20	> 480 mins

## HELMKE DRUM TEST RESULT CLASS 1

PARTICLE SIZE	CUMULATIVE RELEASE RATE (COUNTS/MIN)	SPECIFICATION	CLASS	TEST METHOD
≥ 0.3µm	160	Less than 2,000	1	IEST-RP-CC003.4
≥ 0.5µm	66	2,000 - 20,000	1	IEST-RP-CC003.4
≥ 5.0µm	10	20,000 - 200,000	1	IEST-RP-CC003.4

\*Test carried out on coverall and hood. Typical results.

## LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	15.32 -18.16kg	15.32 -18.16kg
Carton size	W38 L58 H47cm	W38 L58 H47cm
Nett weight	12.52 - 15.36kg	12.52 - 15.36kg
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: **Malaysia**  
HS Code: 6210109000

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