# Isofield Iota Kit

## Steridon Sterile 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) $10^{-6}$

**OVERBOOTS**
Extra long — 50cm knee height
Two ties for added security
Anti-slip sole

### 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

### 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,

20 outer bags per carton liner with twist tie (XS-2XL),

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

Both items are aseptic fold

PRODUCT CODE

REF 80341

| | | | |
|---|---|---|---|
| XSMALL | 80341 XS | XXLARGE | 80341 2XL |
| SMALL | 80341 S | 3XLARGE | 80341 3XL |
| MEDIUM | 80341 M | 4XLARGE | 80341 4XL |
| LARGE | 80341 L | 5XLARGE | 80341 5XL |
| XLARGE | 80341 XL | | |

40°C LATEX TYPE PB[6] STERILE R

Last updated **03 Nov 2026**


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


ISO field

## 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<br>ISO 16603:2004<br>ASTM F1670 | Level 4<br>Class 6 |
| Viral penetration test (liquid challenge : bacteriophage Phi-X174) | ASTM F1671<br>ISO 16604:2004 | Pass<br>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/m² |
| Dry mullen burst strength | TAPPI T403 om-02 | 2100g/cm² |
| 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/m²/day |
| Static decay MD/CD | WSP 40.2 | 0.5/0.5 seconds |
| Slip resistance | ASTM D1894 | 0.6 (Static)<br>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 | 6.23 - 8.31kg | 6.23 - 8.31kg |
| Carton size | W28.5 L47 H38cm | W28.5 L47 H38cm |
| Nett weight | 5.11 - 7.03kg | 5.11 - 7.03kg |
| Air freight pallet | Max height: 129cm<br>Layers: 3<br>Cartons: 18 | Max height: 129cm<br>Layers: 3<br>Cartons: 24 |
| Sea freight pallet | Max height: 167cm<br>Layers: 4<br>Cartons: 24 | Max height: 167cm<br>Layers: 4<br>Cartons: 32 |

## 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, please email us




Made in Malaysia
HS Code: 6210109000

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