Isofield Steridon

Sterile Cleanroom Coverall with Hood



PRODUCT INFO

Sterile Cleanroom coverall with hood

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

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

Colour coded left and 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 10^{-6}

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

Three (3) 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 piece per sealed inner bag,

1 inner bag per sealed outer bag,

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

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

Aseptic fold

PRODUCT CODE

REF 80111

XSMALL	80111 XS	XXLARGE	80111 2XL
SMALL	80111 S	3XLARGE	80111 3XL
MEDIUM	80111 M	4XLARGE	80111 4XL
LARGE	80111 L	5XLARGE	80111 5XL
XLARGE	80111 XL		

40°C LATEX STERILE R

Last updated **20 Oct 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


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 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	

TECHNICAL PROPERTIES

NORM	TEST REFERENCE	EXPLANATION
Sterility Validation Test	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
Particle Generation	IEST-RP-CC003.4 (Helmke Drum Test)	160 counts/min for particles larger than 0.3µm
Static decay MD/CD	WSP 40.2	0.5/0.5 seconds

PERMEATION TEST AGAINST CHEMO DRUGS

CHEMOTHERAPY DRUGS	TEST METHOD	TYPICAL VALUES
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 (SPECIMEN 1/2/3) (MINUTES)
Cyclophosphamide, 20 mg/ml (20,000 ppm)	ASTM F739-20	> 480 min
Doxorubicin HCl, 2mg/ml (2,000 ppm)	ASTM F739-20	> 480 min
Etoposide, 20mg/ml (20,000 ppm)	ASTM F739-20	> 480 min
Fluorouracil, 50 mg/ml (50,000 ppm)	ASTM F739-20	> 480 min
Paclitaxel, 6 mg/ml (6,000 ppm)	ASTM F739-20	> 480 min

LOADING

	EURO-PALLET	STANDARD PALLET
Pallet size	W80 L120cm	W100 L120cm
Gross weight	5.56 - 6.93kg	5.56 - 6.93kg
Carton size	W28 L43 H31cm	W28 L43 H31cm
Nett weight	4.76 - 6.13kg	4.76 - 6.13kg
Air freight pallet	Max height: 139cm Layers: 4 Cartons: 24	Max height: 139cm Layers: 4 Cartons: 32
Sea freight pallet	Max height: 170cm Layers: 5 Cartons: 30	Max height: 170cm Layers: 5 Cartons: 40

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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