

3DESIGN INDUSTRY



Introducing the Steridon by Isofield. The latest addition to the Isofield range, the Steridon is an aseptically presented coverall which can be donned in less than a minute.

With an integrated facemask option, it is the first garment to be validated for sterility through X-Ray. Designed for Grade A / B, ISO Class 4 & 5 Cleanrooms, the Steridon is manufactured from a unique material blend that offers exceptional levels of comfort, safety, and cleanliness.





GIVE ME a minute

The Steridon can be donned in less than 40 seconds, and less than 60 seconds for the integrated facemask option.

For production areas with multiple operators the cost savings on changing times could be significant.











We understand SOP's differ. To ensure Steridon complies with your protocol, it comes in 2 options, with or without mask.



STERIDON DESIGN | 4



EXTRA FABRIC in all the right places

The Steridon gives your body room to breathe.

No more tension! Our ergonomic design allows for a full range of motion around the neck, shoulders and torso. The design ensures that even whilst moving around the cleanroom the risk of unwanted skin exposure is dramatically reduced.

The elasticated hood, wrists and ankles are encapsulated, latex-free, and all seams are bound to prevent the egress of particles into the cleanroom.



HEAD & SHOULDERS above

Our extended three-panel hood design ensures that the forehead is appropriately covered to limit skin exposure, and provides a solid platform for your goggle seal.

Adding extra fabric around the neck and shoulders ensures that the hood stays in place no matter which way you turn.





INTEGRATED FACEMASK - ON CLOSER INSPECTION

The Perfect Hybrid.

We understand that having ties gives you control over the facemask donning process. Ties give you the secure snug fit that elasticated alternatives simply can't.

The Steridon solves this with our unique approach to secure mask donning. Each 230mm mask has a channelled set of top ties set into the construction which quickly guides you to the correct position, speeding up the donning process. The base of the mask is fully integrated to ensure no particles can escape.



Tri-laminate monolithic film

Excellent fluid & viral protection

Anti-static, soft & breathable

Suitable for ISO Class 4 & 5, Grade A/B cleanroom applications where protection against fluids, viruses, and chemotherapy are required



Repellent

Antistatic treated

Low-linting (Helmke Drum Test Class 1)

MIDDLE LAYER

Impervious breathable monolithic film

Allows moisture vapor to pass through

NNER LAYEF

Soft to touch Comfortable Breathable

> ISO field



ASEPTICALLY

The Steridon is packed inside-out ensuring that when the package is opened, only the inside of the garment is touched, maintaining the sterile field.

Each Steridon is packed in a double layer of ISO Class 4 & 5 compatible cleanroom grade HDPE packaging, vacuum sealed, and then packed into a HDPE Carton liner.





THE FUTURE OF STERILIZATION



The Steridon is the first Cleanroom garment in the world to be validated sterile using X-ray.

More environmentally friendly than gamma irradiation, more sustainable, and more stable from a supply chain perspective, X-ray offers companies with ambitious environmental goals an excellent option.

STERIDON DATA SUMMARY

STERIDON WITH HOOD

REF 80111

SMALL 80111S MEDIUM 80111M LARGE 80111L XLARGE 80111XL XXLARGE 80111XXL 3XLARGE 80111XXXL **4XLARGE** 80111XXXXL 5XLARGE 80111XXXXXL

STERIDON WITH HOOD & INTEGRATED FACEMASK

REF 80231

80231S **SMALL** 80231M MEDIUM 80231L LARGE 80231XL XLARGE XXLARGE 80231XXL 80231XXXL 3XLARGE 4XLARGE 80231XXXXL 5XLARGE 80231XXXXXL

PRODUCT INFO

GMP Grade A & B compatible ISO Class 4 & 5 cleanroom compatible Aseptic fold Donning in less than one minute

DESIGN

Latex-free, enclosed and elasticated face, wrists & ankles Ergo-fit design at back and shoulders Bound seams Integrated facemask with guided tie-on system*

*Available for Steridon with integrated facemask

FABRIC

52gsm tri-laminate fabric Excellent fluid and viral protection Soft, comfortable, and breathable

ASEPTICALLY PACKED

Aseptically presented fold Colour coded left & right inner tabs Removable external tabs at zipper to maintain sterile field

STERILIZATION

Validated for sterility X-Ray Sterility Assurance Level (SAL) 10⁻⁶

QUALITY ASSURANCE

Manufactured in a facility operating under ISO 9001:2015 quality management system

Processed in a NEBB certified ISO Class 5 cleanroom

APPLICATIONS

Grade A & B, ISO Class 5 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



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

PHYSICAL PROPERTIES

PHYSICAL PROPERTIES	TEST METHOD	TYPICAL VALUES
Basis weight	ASTM D3776	52 g/m²
Dry mullen burst strength	TAPPI T403 om-02	2100 g/cm²
Tensile strength	ASTM D5034 (Grab CD)	7500 g (16.5 lbf)
	ASTM D5034 (Grab MD)	11000 g (24.5 lbf)
Trapezoid tear MD	ASTM D5733-95	2400 g
Hydrostatic head with screen	AATCC 127	200 cm
Wet peel CD (inner/ outer)	ASTM F904-98	50/100 g/2 in
Moisture vapor transmission rate (MVTR)	ASTM E96 Procedure D	1400 g/m²/day
Helmke drum particle count	IEST-RP-CC003.4	Class I (<2000)
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

PACKAGING

1 piece per sealed inner cleanroom bag

1 inner bag per sealed outer bag

20 outer bags per carton liner with twist tie

20 pieces per carton (S-XXL)

15 Pieces per carton (3XL-5XL)

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









free sample? SURE!....

ASIA

Isofield Sdn. Bhd. 6 Jalan Gudang 16/9, Seksyen 16, 40200, Shah Alam, Selangor, Malaysia, T+603 5512 1709

EUROPE

Isofield (Ireland) Ltd. 70 Northumberland Road, Ballsbridge, Dublin 4, Dublin, Ireland T +44(0) 1638 676239

info@isofield.com www.isofield.com