

ComfortGuard®

Spunbond Film Laminate Isolation Gowns

CODE	DESCRIPTION	SIZE	CASE QTY	CASE DIMENSIONS
60-3094	Spunbond Film Laminate Isolation Gown, Over-The-Head	L	100	21x15x14"(53x38x34cm)
60-3095	Spunbond Film Laminate Isolation Gown, Over-The-Head	XL	100	21x15x14"(53x38x34cm)

Materials

- Two- Layered Polypropylene (PP)/Polyethylene (PE) Film

Product Attributes

- AAMI Level II Protection Level
- Thumbhook

Sterilization

Non-Sterile: If a product is delivered non-sterile and is ultimately for use in sterile environments, it is intended to be sterilized by the re-packer. This includes further packaging and sterilization according to the validated processes of the re-packer. These products are to be sterilized by ethylene oxide (EO). Other methods of sterilization have not been validated by Alleset.

Shelf Life

Non-Sterile: Established at 5 years based upon sterile packaged product aging studies and normal warehouse storage conditions. After 5 years, the product should be performance tested to ensure compliance to specifications.

Product Certifications/Standards

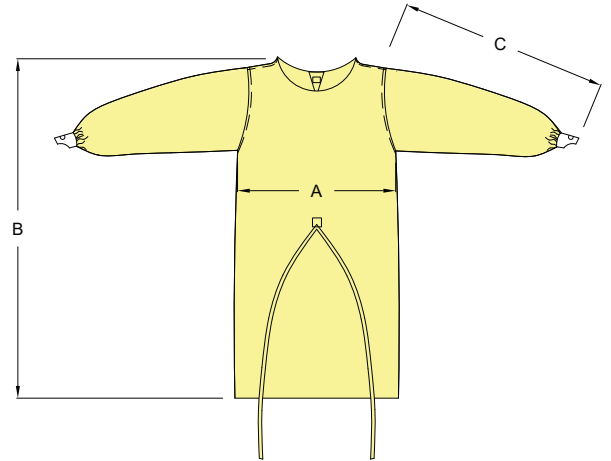
- Conforms to ASTM F3352 Standard Specification for Isolation Gowns
- Intended for Use in Healthcare Facilities requirements
- Meets EN 13795:2011 Standard Performance
- Conforms to EN ISO 22610:2006, resistance to wet bacterial penetration
- Conforms to EN ISO 22612:2005, resistance to dry microbial penetration
- Conforms to ISO/FDIS 16603, resistance of protective clothing material to penetration by blood and body fluids- using synthetic blood
- Conforms to ISO 109931 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process
- Conforms to ISO 10993-5 2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- Conforms to ISO 10993-10 2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- Class 1 per 16 CFR part 1610 (flammability testing)
- CE certified as class I, according to MDR 2017/745, Annex VIII, Rule 1
- Meets ANSI/AAMI PB70:2012 Level 2 Liquid Barrier Protection

Manufacturing Certifications/ Registrations

- EN ISO 13485:2016

Storage

- General warehouse conditions



Code	A: Chest Width	B: Total Length	C: Sleeve Length
60-3094	28.5" (72cm)	46" (117cm)	27.5" (70cm)
60-3095	30.5" (77cm)	48" (122cm)	29.5" (75cm)
Tolerance	±0.5" (1.27cm)	±0.5" (1.27cm)	±1" (2.54cm)



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Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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