ComfortGuard®

Spunbond Film Laminate Isolation Gowns

	CODE	DESCRIPTION	SIZE	CASE QTY	CASE DIMENSIONS
N	60-3107	Spunbond Film Laminate Isolation Gown, Full Coverage Gown, Hook and Loop Neck Closure, Tie Waist	L	100	21x14x14" (53x36x36cm)
N	60-3108	Spunbond Film Laminate Isolation Gown, Full Coverage Gown, Hook and Loop Neck Closure, Tie Waist	XL	100	21x14x14" (53x36x36cm)
N	60-3109	Spunbond Film Laminate Isolation Gown, Full Coverage Gown, Knit Cuff, Hook and Loop Neck Closure	L	100	21x14x14" (53x35x36cm)
N	60-3110	Spunbond Film Laminate Isolation Gown, Full Coverage Gown, Knit Cuff, Hook and Loop Neck Closure	XL	100	21x14x14" (53x35x36cm)

Materials

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

Product Attributes

- Non Stitch, thermal bonded sleeve seams
- Full coverage protection

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-packager. This includes further packaging and sterilization according to the validated processes of the re-packager. 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 Facilities1requirements
- 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 materials 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

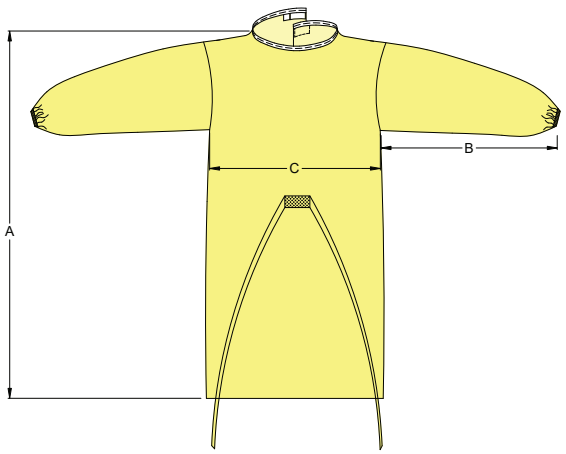
Manufacturing Certifications/ Registrations

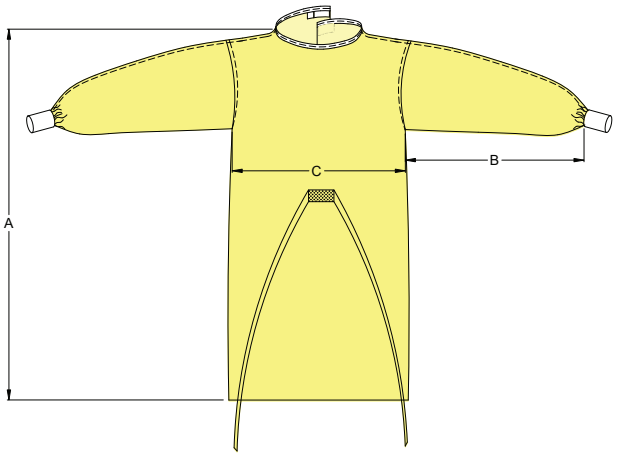
- EN ISO 13485:2016

LATEX · PHT DEHP · CN/VN · NON-STERILE

Storage

- General warehouse conditions





Code	A: Total Length	B: Sleeve Length	C: Chest Width
60-3107	46" (117cm)	23" (58cm)	29" (74cm)
60-3108	48" (122cm)	24" (61cm)	31" (79cm)
60-3109 (w/ Knit Cuff)	46" (117cm)	23" (58cm)	29" (74cm)
60-3110 (w/ Knit Cuff)	48" (122cm)	24" (61cm)	31" (79cm)
Tolerance	±1" (2.54cm)	±1" (2.54cm)	±1" (2.54cm)

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

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