


ComfortGuard® Film Gown

CODE	DESCRIPTION	SIZE	CASE QTY	CASE DIMENSIONS
 60-3080	Film Gown, Thumbs up, Blue	L	75	25x8x13" (63x20x33cm)
 60-3081	Film Gown, Thumbs up, Blue	XL	75	25x8x13" (63x20x33cm)

Materials

-  Blue Polyethylene (PE) Film

Product Attributes

- Tie waist
- Open back
- Thumb hook cuff

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

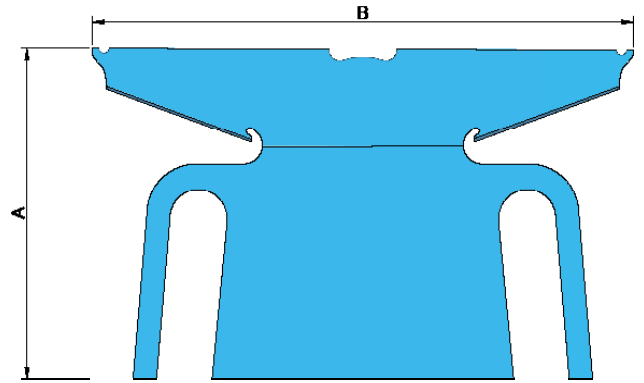
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

Manufacturing Certifications/ Registrations

- EN ISO 13485:2016

Storage

- General warehouse conditions



Code	B: Total Length	C: Chest Length
60-3080	48" (122cm)	79" (200cm)
60-3081	49" (124cm)	80" (204cm)
Tolerance	±1" (2.54cm)	±1" (2.54cm)



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SM-TDS-003 2023
Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.



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