Surgical Drapes

Ophthalmic



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N	80-08139G	Ophthalmic Drape w/ Aperture and Fluid Collection Pouch,61.5x91.5" (156x232cm)	TBD	TBD
S	80-08139G-S	Ophthalmic Drape w/ Aperture and Fluid Collection Pouch,61.5x91.5" (156x232cm)	14	16x11x17" (40x27x42cm)

Materials

- Multilayered SMS Material with Antistatic Properties and Alcohol Repellency
- HydraGuard® Absorbent Reinforcement
- Oclear Polyethylene (PE) Film

Product Attributes

- · Adhesive incise area with oval fenestration
- Fluid collection pouch
- · Malleable breather bar

Sterilization

Sterile: Sterilized by EO (ethylene oxide). Product is sterile unless the package has been damaged or opened.

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 repackager. 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

Sterile: 5 years

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

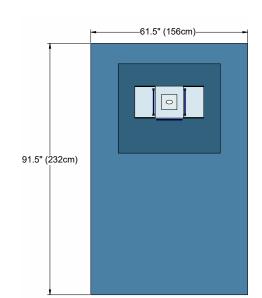
• CE certified as Class I, according to MDR 2017/745, Annex VIII, Rule 1

Manufacturing Certifications/Registrations

- EN ISO 13485:2016
- · Medical Device Single Audit Process Certified

Storage

· General warehouse conditions













Alleset 4142 Industry Way Flowery Branch, GA 30542, www.alleset.com SM-TDS-003 2023 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.

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