CODE

# Surgical Drapes Ophthalmic

DESCRIPTION



CASE OTV CASE DIMENSIONS

	CODE	DESCRIPTION		(	CASE QTY	CASE DIMENSIONS
	80-08119	Ophthalmic Drape w/ Aperture and Saddlebag Fluid 55x71" (140x180cm)	d Collection Pouch,		50	23x14x17" (58x36x43cm)
S	80-08119-S	Ophthalmic Drape w/ Aperture and Saddlebag Fluid 55x71" (140x180cm)	d Collection Pouch,		17	16x11x16.5" (40x27x42cm)
Mat	erials					
Multilayered SMS Material with Antistatic Properties and Alcohol Repellency						55" (140cm)
00	Clear Polyethyle	ne (PE) Film				
Product Attributes						0
<ul> <li>Adhesive incise area with oval fenestration</li> <li>Fluid collection pouch</li> <li>Malleable breather bar</li> </ul>				71" (180cm)		
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, USA www.alleset.com SM-TDS-003 2023 Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes. THINK.MAKE.PROTECT.



GRI Medical & Electronic Technology Co., LTD 1805 Honggao Road, 314031 Jiaxing, Zhejiang PEOPLE'S REPUBLIC OF CHINA www.alleset.com US FDA Establishment Registration #3004911384



Emergo Europe B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands www.emergobyul.com

www.emergob



A GRI COMPANY