

# Surgical Drapes

## Obstetrics/Gynecology

CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
80-14105	Under Buttocks Drape w/ Fluid Collection Pouch, 46x35" (117x90cm)	90	21x16x17" (54x40x42cm)

### Materials

- Blue Polyethylene (PE) Film
- Hydra™ Absorbent Reinforcement
- Fluid Collection Pouch, Clear Polyethylene (PE) Film

### Product Attributes

- Film fabric reinforced
- Absorbent reinforcement material for fluid management
- Clear film fluid collection pouch with graduated markings and a suction port

### 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

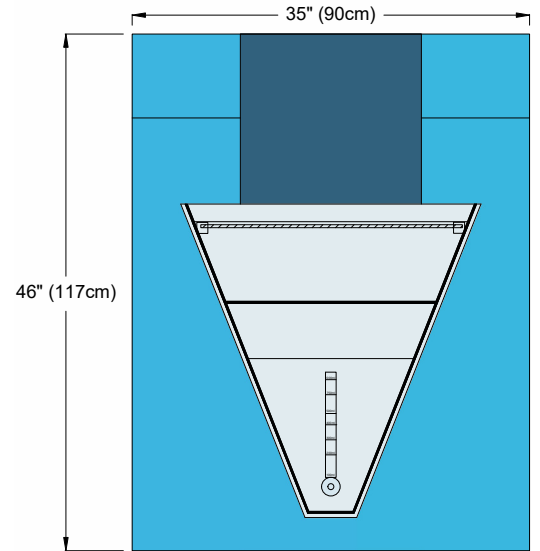
- CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1

### Manufacturing Certifications/Registrations

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

### Storage

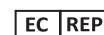
- General warehouse conditions



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.



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

