Equipment Covers

ECO² Endo Camera



	CODE	DESCRIPTION (WxL)	CASE QTY	CASE DIMENSIONS
N	E44-0796E	ECO ² Camera Cover, Elastic Tip, 7x96" (18x244cm)	100	11x9x10" (28x23x25cm)
S	E44-0796E-S	ECO ² Camera Cover, Elastic Tip, 7x96" (18x244cm)	25	11x9x10" (28x23x25cm)

Materials

- O Clear Polyethylene (PE) Film
- Kraton™ Conformable Fenestration Material

Product Attributes

- · Conformable elastic tip
- · Adhesive polyethylene securement strap
- · Incorporates sustainable materials which enhance product biodegradation.

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

- Sterile: CE certified as Class I, according to MDD93/42/EEC Annex IX, Rule 1
- Non-Sterile: 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

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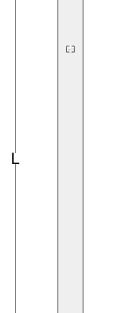




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EC REP

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