Equipment Covers

FCO² C-Arm



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N	E46-CARM1	ECO ² C-Arm Cover, Universal w/ Rubber Bands and Clips, 41x65" (104x165cm)	100	18x13x11" (46x34x28cm)
S	E46-CARM1-S	ECO ² C-Arm Cover, Universal w/ Rubber Bands and Clips, 41x65" (104x165cm)	50	18x13x11" (46x34x28cm)

Materials

○ ECO² Clear Polyethylene (PE) Film

Product Attributes

- · Certain components of this product incorporate ECO2 sustainable materials which enhance product biodegradability
- · Clear film helps prevent image distortion
- Versatile design
- · Rubber band and clip securement

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,
- Non-Sterile: CE certified as Class I, according to MDR 2017/745 Annex VIII, Rule 1
- ASTM D5511-12 Standard Test Method for Determining Anaerobic Biodegradation of Plastics Materials Under High-Solids Anaerobic **Digestion Conditions**

Manufacturing Certifications/Registrations

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

Storage

· General warehouse conditions





Flowery Branch, GA 30542,

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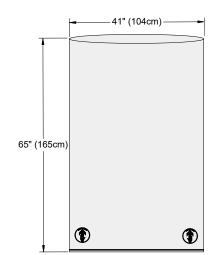




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EC REP

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Country of Origin Abbreviations per ISO 3166-1, Alpha-2 Codes.







