Equipment Cover

SANI-SLEEVE™



	CODE	DESCRIPTION	CASE QTY	CASE DIMENSIONS
N	47-SS0365	SANI-SLEEVE™ Equipment Cover, w/ Insert Assist Ring, 2.3x65" (6x165cm)	200	20x14x20" (50x35x50cm)
S	47-SS0365-S	SANI-SLEEVE™ Equipment Cover, w/ Insert Assist Ring, 2.3x65" (6x165cm)	100	20x14x20" (50x35x50cm)

Materials

Clear Polyethylene (PE) Film

Red Tape

Blue Tape

White Polypropylene (PP)

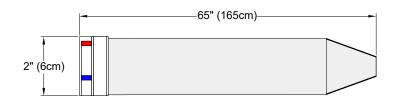
Product Attributes

- · Plastic ring allows for proper application of sleeve
- · Includes two tape strips
- Tapered opening

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 2024

WWW.alleset.com SM-TDS-003 2024 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 EC REP

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