

ChemoGuard™

Chemotherapy Gowns and Sleeves

CODE	DESCRIPTION	SIZE	CASE QTY	CASE DIMENSIONS
N 60-3199	Chemotherapy Gown	M	60	20x12.5x12.5" (52x32x32cm)
S 60-3199-S	Chemotherapy Gown	M	60	20x12.5x12.5" (52x32x32cm)
N 60-3200	Chemotherapy Gown	L	60	21x14x14" (54x35x35cm)
S 60-3200-S	Chemotherapy Gown	L	60	21x14x14" (54x35x35cm)
N 60-3201	Chemotherapy Gown	XL	60	21x15x14" (54x39x35cm)
S 60-3201-S	Chemotherapy Gown	XL	60	24x16x14" (61x41x35cm)
N 60-3210	Chemo Sleeve, Elastic at Wrist and Top	Universal	120	16x13x10" (40x32x25cm)
S 60-3210-S	Chemo Sleeve, Elastic at Wrist and Top	Universal	100	16x13x10" (40x32x25cm)

Materials

- Polypropylene (PP)/ Polyethylene (PE) Film

Product Attributes

- Full coverage gown, knit cuffs
- Gown and sleeve seams pass ASTM D6978 - 05 Testing Standards
- Virtually lint-free poly-coated spunbond
- Lightweight, closed back design

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 re-packager. 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

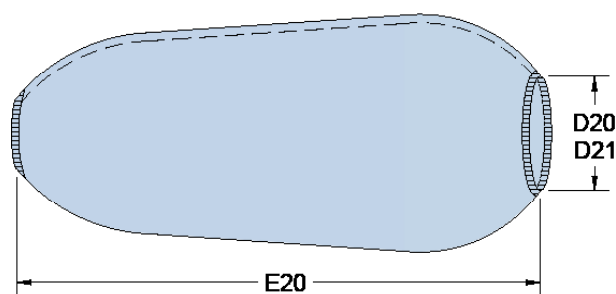
- Conforms to ASTM D6987-05 Standard Practices for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs
- Meets the USP 800 General Chapter <800> Guidelines
- Conforms to EN 14126:2003 performance requirement for protective clothing against infective agents
- Conforms to ISO 16603: 2004 Resistance to penetration by blood and body fluids; Class 6
- Conforms to ISO 16604: 2004 Resistance to penetration by blood-borne pathogens-Testing method using Phi-X174 bacteriophage; Class 6
- Conforms to ISO 22610: 2018 Resistance to wet microbial penetration; Class 5
- Conforms to ISO 22611: 2003 Resistance to liquid aerosol penetration; Class 3
- Conforms to ISO 22612: 2005 Resistance to dry microbial penetration; Class 3
- Conforms to IEST-RP-CC003.4: 2011, Helmek test; Category II, Sterile and nonsterile
- Meets ANSI/AAMI PB70:2012 Level 2 Performance Requirements
- CE certified as Category 1 PPE per Regulation (EU) 2016/425

Manufacturing Certifications/ Registrations

- EN ISO 13485:2016

Storage

- General warehouse conditions



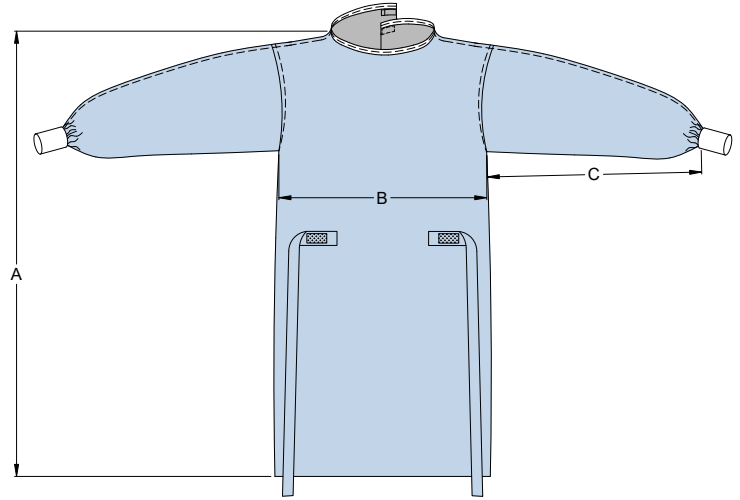
Chemo Sleeve

Code	D20: Bicep Opening Relaxed	D21: Bicep Opening Extended	E20: Sleeve Inseam
60-3210 (S/NS)	5.5" (14cm)	9.75" (25cm)	23.5" (60cm)
Tolerance	±0.5" (1.27cm)	±0.5" (1.27cm)	±0.5" (1.27cm)

ChemoGuard™

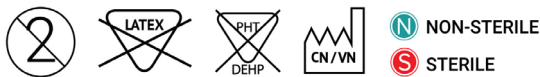
Chemotherapy Gowns and Sleeves

ASTM Standard Test Methods			
ASTM Standard	Permeation Rate	Temperature	Drugs
D6978-05	0.01 µg/cm ² /min	35± 2°C	Seven required + two optional



Test Chemotherapy Drug	Minimum Breakthrough Detection Time (Minutes)
Carmustine	No breakthrough up to 240 minutes
Cisplatin	No breakthrough up to 240 minutes
Cyclophosphamide (Cytosan)	No breakthrough up to 240 minutes
Cytarabine	No breakthrough up to 240 minutes
Dacarbazine (DTIC)	No breakthrough up to 240 minutes
Doxorubicin Hydrochloride	No breakthrough up to 240 minutes
Daunorubicin HCl	No breakthrough up to 240 minutes
Etoposide (Toposar)	No breakthrough up to 240 minutes
Fluorouracil	No breakthrough up to 240 minutes
Ifosfamide	No breakthrough up to 240 minutes
Methotrexate	No breakthrough up to 240 minutes
Mitomycin C	No breakthrough up to 240 minutes
Mitoxantrone,	No breakthrough up to 240 minutes
Paclitaxel (Taxol)	No breakthrough up to 240 minutes
Thiotepa	No breakthrough up to 240 minutes
Vincristine Sulfate	No breakthrough up to 240 minutes

Code	A: Total Length	B: Chest Width	C: Sleeve Length
60-3199 (S/NS)	44" (111.7cm)	26.5" (67.3cm)	21.5" (54.6cm)
60-3200 (S/NS)	46" (116.9cm)	28.5" (72cm)	22.5" (57cm)
60-3201 (S/NS)	48" (122cm)	30.5" (77cm)	23.5" (60cm)
Tolerance	±1" (2.54cm)	±1" (2.54cm)	±1" (2.54cm)



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

EC REP Alleset Limited B.V.
Kingsfordweg 151,
1043 GR Amsterdam,
The Netherlands
www.alleset.com