

# PRODUCT INFORMATION

## cleo® saphir Protective sleeve cover

for use with cytostatic & biological substances

### Application area and properties

- + **Maximum protection and comfort:** Type-tested and certified as complex PPE<sup>1)</sup> of category III; chemical protective clothing type PB [4], infection protective clothing type PB [4]-B; partial body protection. Optimum personal and product protection (sterile version); impermeable to liquids in the coated area; knitted or elasticated cuffs at the bottom; elasticated cuffs at the top; conical cut for pleasant wearing comfort; material is latex-free, low in lint and particles; available in 2 different sizes; sterile and non-sterile version.
- + **Area of application:** Protective sleeve cover for handling CMR<sup>2)</sup> drugs (e.g. cytostatic and virostatic agents) and biological agents<sup>3)</sup> (e.g. bacterial and viruses).
- + **Protective barrier:** Liquid impermeable coating with a high barrier function of the coated material against bacteria and viruses.
- + **Protection capacity:** Protection against penetration of chemicals and biologically contaminated liquids, spray-tight partial protective clothing according to DIN EN 14605, tested permeation protection according to the permeation list given here. No guarantee for CMR<sup>2)</sup> drugs or chemicals not listed. In case of exposure to biological agents and chemicals not corresponding to the level of protective clothing, permeation of the protective sleeves may occur type PB [4]-B.
- + **Directions for use:** Always wear with the coated side on the outside and the seam pointing downwards. Keep away from open flames and heat sources.
- + **Change interval:** Daily, i.e. use up to a maximum of 8 hours<sup>4)</sup>; in case of visible contamination immediately! Single use only!
- + **Before use:** Check for any damage! Do not use damaged sleeve covers!
- + **Disposal:** Waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in case of heavy contamination, waste requiring special supervision<sup>5)</sup> (waste code: 18 01 08\*<sup>6)</sup> or 18 01 03\*<sup>7)</sup> in accordance with 2000/532/EC); collect and dispose of waste separately!

<sup>1)</sup>: Personal protective equipment. <sup>2)</sup>: Carcinogenic mutagenic toxic to reproduction. <sup>3)</sup>: Microorganisms, including genetically altered microorganisms, cell cultures and human endoparasites, which could cause infections or allergies or have toxic effects. <sup>4)</sup>: Dependent on the utilized chemicals / CMR-drugs or biological materials. <sup>5)</sup>: Any waste marked with an asterisk (\*) is considered hazardous waste pursuant to Article 1(4), first indent, of Directive 91/689/EEC on hazardous waste. <sup>6)</sup>: Cytotoxic and cytostatic drugs. <sup>7)</sup>: Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.

### Types

Size	S/M	L/XL
Length of arm covers (cm):	ca. 52 cm	ca. 52 cm
<b>Blue sleeve covers with knitted cuff</b>		
Width of arm covers (cm)	18 cm	21 cm
Item No. (non-sterile) 50 pairs	6010	6000
Item No. (sterile) 40 pairs	6011	6001
<b>Light blue sleeve covers with elasticated cuff</b>		
Item No. (non-sterile) 50 pairs		6200
Item No. (sterile) 40 pairs		6300

## Material properties

<b>Material</b>	Spun polypropylene
<b>Material properties</b>	Latex-free
<b>Material weight</b>	42 g/m <sup>2</sup>
<b>Liquid-tight coating</b>	Polyethylene
<b>Coating thickness</b>	approx. 25 µm
<b>Total weight of gown</b>	20-36 g
<b>pH-value nonwoven with coating &amp; knitted cuffs</b>	6.2
<b>MAK amines / AZO dyes</b>	not detectable

## Protection from mechanical hazards

Mechanical properties of material tested in accordance with DIN EN 14325. Coding with regard to the performance classes as follows:

Requirements	Performance class	
Abrasion resistance (1-6) acc. EN 530	1 (visual inspection)	
Puncture resistance (1-5) acc. EN 863	1	
Seam strength (1-5) gem. ISO 13935-2	2	
Tensile strength (1-5) acc. ISO 13934-1	2	
Flex cracking (1-6) acc. ISO 7854	2	
Trapezoidal tear strength (1-5) acc. ISO 9073-4	Longitudinal: 4	Transverse: 3

## Protection from chemical hazards

**Permeation**<sup>8)</sup> tested in accordance with DIN EN 16523-1.

Breakthrough times<sup>9)</sup> [min] / performance classes<sup>10)</sup> (1-6) were established for the following chemicals:

Chemical	Breakthrough time [min]	Performance class
Seam testing carmustine (3.3 mg/ml)	> 480	6
Carmustine (3.3 mg/ml)	> 480	6
Cisplatin (1.0 mg/ml)	> 480	6
Cyclophosphamide (20.0 mg/ml)	> 480	6
Daunorubicin HCl (5mg/ml)	> 480	6
Doxorubicine HCl (2 mg/ml)	> 480	6
Etoposide (20.0 mg/ml)	> 480	6
5-Fluorouracil (50.0 mg/ml)	> 480	6
Formaldehyde 4%	> 480	6
Gemcitabine (38.0 mg/ml)	> 480	6

Isopropanol 70%	> 480	6
Methotrexate (25 mg/ml)	> 480	6
Caustic Soda 30%	> 480	6
Paclitaxel (6mg/ml)	> 480	6
ThioTEPA (10.0 mg/ml)	> 480	6
Vincristine (1 mg/ml)	> 480	6

<sup>8)</sup>: Movement of a chemical through a material on a molecular level. <sup>9)</sup>: At a permeation rate of 1 µg/min·cm<sup>2</sup>

<sup>10)</sup>: The performance class does not reflect the actual duration of protection at the workstation.

## Protection from infectious agents

**Penetration<sup>11)</sup>** tested in accordance with EN 14126 fulfilled. Test results as follows:

Resistance to penetration by blood and body fluids in acc. to ISO 16603.

Hydrostatic pressure [kPa]	Performance class (1-6) <sup>12)</sup>
20 kPa	6

Resistance to penetration of pathogens, which are blood transmitted using the virus Phi-X174 to ISO 16604.

Hydrostatic pressure [kPa]	Performance class (1-6) <sup>12)</sup>
20 kPa	6

Resistance to wet bacterial penetration in accordance with EN ISO 22610.

Breakthrough time [min]	Performance class (1-6) <sup>12)</sup>
t > 75	6

Resistance to penetration of biologically contaminated aerosols in accordance with ISO/DIS 22611.

Penetration ratio (log)	Performance class (1-3) <sup>12)</sup>
log > 5	3

Resistance to dry microbial penetration in accordance with ISO 22612.

Penetration (log of the CFU <sup>13)</sup> )	Performance class (1-3) <sup>12)</sup>
log of CFU < 1	3

<sup>11)</sup>: Entry of solid, liquid or gaseous agents through macroscopic holes (flaws, seams).

<sup>12)</sup>: The performance class does not reflect the actual period of protection at the workplace! <sup>13)</sup>: CFU = Colony forming units

## Sterilization

**Procedure**

Fumigation with ethylene oxide

## Care instructions

- + Do not wash
- + Do not iron
- + Do not tumble dry
- + Do not dry clean

---

## CE-marking

In accordance to the PPE regulation EU 2016/425 for complex PPE category III, on the basis of DIN EN 14605; EN 14126; EC-type test and control measures by the notified body „2797“. Documented by EC type test certificate no. CE 715808. The EC-declaration of conformance and the EC-Type test certificate can be downloaded at [www.berner-safety.de](http://www.berner-safety.de).

---

## Notified body "2797"

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, NL

---

## Quality management system

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH in accordance with DIN EN ISO 9001:2015. Regular **audits and production site inspections** guarantee the quality of our products.

---

## Storage and transport conditions

- + Dark (protect from direct UV light and sunlight)
- + Cool (+5 to +40°C)
- + Dry (relative humidity 30% - 60%)
- + No contact with pointed and/or sharp objects

---

## Shelf life

Unsterile version: 5 years

Sterile version: 5 years

---

## Distributor

**Berner International GmbH**, Werner-von-Siemens-Str. 19, 25337 Elmshorn

Tel: +49 4121 43560, Fax: +49 4121 435620 [info@berner-safety.de](mailto:info@berner-safety.de), [www.berner-safety.de](http://www.berner-safety.de)

---