PRODUCT INFORMATION
cleo® saphir
Protective gown for use with cytostatic & biological substances

Application area and properties

+ **Maximum protection and comfort:** Type tested and certified as complex PPE[1)] (category III); chemical protective type PB [4], protective clothing against infection type PB [4]-B; partial body protection. Optimal operator and product protection (sterile version); impervious to liquids on the arms and front, which are coated; raised neckline; breathable back; pleasant and comfortable to wear; material is low in lint with low particle generation and latex-free; practical velcro fastening in the neck area; knitted or elasticated cuffs at the sleeve ends.
+ **Area of application:** Protective gown for handling CMR[2)] drugs (e.g. cytostatic and virostatic agents) and biological agents[3)] (e.g. bacterial and viruses).
+ **Protective barrier:** Liquid-impervious coating. In compliance with EN 14126:2003 a high barrier function of the coated material against bacteria and viruses can be assumed.
+ **Protection capacity:** Protection from all CMR drugs or chemicals cannot be guaranteed! In case of exposition to biological hazardous materials, which do not correspond to the degree of imperviousness of the protective clothing, biocontamination of the wearer is possible.
+ **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[4)]; in case of visible contamination immediately! Single use only!
+ **Before use:** Check for any damage! Do not use damaged gowns!
+ **Disposal:** Waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in case of heavy contamination, waste requiring special supervision[5)] (waste code: 18 01 08*[6)] or 18 01 03*[7)] in accordance with 2000/532/EC); collect and dispose of waste separately!

[1)]: Personal protective equipment. [2)]: Carcinogenic mutagenic toxic to reproduction. [3)]: Microorganisms, including genetically altered microorganisms, cell cultures and human endoparasites, which could cause infections or allergies or have toxic effects. [4)]: Dependent on the utilized chemicals / CMR-drugs or biological materials. [5)]: 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. [6)]: Cytotoxic and cytostatic drugs. [7)]: Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.

Types

Blue gown with knitted cuffs				
Size	**S**	**M**	**L**	**XL**
Item No. (non-sterile) 15 pieces	6700	6800	6900	100072 (10 pieces)
Item No. (sterile) 10 pieces	6701	6801	6901	100073
Light blue gown with elasticated cuffs				
Size	**S**	**M**	**L**	**XL**
Item No. (non-sterile) 15 pieces	-	6500	6550	-
Item No. (sterile) 10 pieces	-	6600	6650	-

Material properties

Material	Spun polypropylene
Material properties	Latex-free
Material weight	42 g/m²

Liquid-tight coating	Polyethylene
Coating thickness	approx. 25 µm
Total weight of gown	120-141 g
pH-value nonwoven with coating & knitted cuffs	6.2
MAK amines / AZO dyes	not detectable

Protection from mechanical hazards

Mechanical properties of material tested in accordance with DIN EN 14325:2004. Coding with regard to the performance classes as follows:

Requirements	**Performance class**	
Abrasion resistance (1-6) acc. EN 530:2010	1 (visual inspection)	
Puncture resistance (1-5) acc. EN 863:1995	1	
Seam strength (1-5) gem. ISO 13935-2:1999	3	
Tensile strength (1-5) acc. ISO 13934-1:1999	2 / 1*	
Flex cracking (1-6) acc. ISO 7854:1997	2	
Trapezoidal tear strength (1-5) acc. ISO 9073-4:1997	Longitudinal: 4	Transverse: 3
*coated / uncoated material		

Protection from chemical hazards

Permeation[1)] tested in accordance with DIN EN 16523-1:2015.
Breakthrough times[2)] [min] / performance classes[3)] (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
Etoposide (20.0 mg/ml)	> 480	6
5-Fluorouracil (50.0 mg/ml)	> 480	6
Gemcitabine (38.0 mg/ml)	> 480	6
ThioTEPA (10.0 mg/ml)	> 480	6
NaOH 30%	> 480	6
Formaldehyde 4%	> 480	6
Isopropanol 70%	> 480	6

[1)]: Movement of a chemical through a material on a molecular level. [2)]: At a permeation rate of 1 µg/min·cm²
[3)]: The performance class does not reflect the actual duration of protection at the workstation.

Protection from infectious agents

Penetration[1)] tested in accordance with EN 14126:2003 fulfilled. Test results as follows:

Resistance to penetration by blood and body fluids in acc. to ISO 16603:2004.

Hydrostatic pressure [kPa]	Performance class (1-6)[2)]
20 kPa	6

Resistance to penetration of pathogens, which are blood transmitted using the virus Phi-X174 to ISO 16604:2004.

Hydrostatic pressure [kPa]	Performance class (1-6)[2)]
20 kPa	6

Resistance to wet bacterial penetration in accordance with EN ISO 22610:2006.

Breakthrough time [min]	**Performance class (1-6)**[2)]
t > 75	6

Resistance to penetration of biologically contaminated aerosols in accordance with ISO/DIS 22611:2003.

Penetration ratio (log)	**Performance class (1-3)**[2)]
log > 5	3

Resistance to dry microbial penetration in accordance with ISO 22612:2005.

Penetration (log of the CFU[3)])	**Performance class (1-3)**[2)]
Log of CFU < 1	3

[1)]: Entry of solid, liquid or gaseous agents through macroscopic holes (flaws, seams).

[2)]: The performance class does not reflect the actual period of protection at the workplace! [3)]: CFU = Colony forming units

Sterilisation

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 14605:2005 +A1:2009; EN 14126:2003; 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.

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

Non-sterile version: 5 years from the date of manufacture
Sterile version: 4 years from the date of sterilisation

Distributor

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