

Protective Gown for Use with Cytostatic Agents 



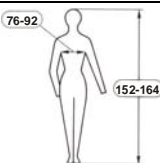
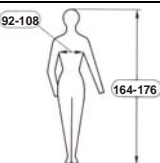
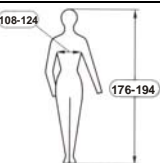
Area of Application and Features

- **Maximum protection and comfort:** type tested and certified as complex PPE¹⁾ (category III); 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; practical Velcro fastening in the neck area; knitted or elasticated cuffs at the sleeve ends.
- **Area of application:** protective gown for handling CMR²⁾ drugs (e.g. cytostatic and virustatic agents)
- **Protection capacity:** protection from all CMR drugs or chemicals is not guaranteed.
- **Protective overall replacement interval:** daily, i.e. use for a maximum of 8 hours³⁾; immediately in the event of visible contamination. Do not reuse!
- **Protective barrier:** coating that is impervious to liquids on the arms and front.
- **Before use:** check for damage. Do not use damaged gown.
- **Disposal:** waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in the event of heavy contamination, waste requiring special supervision (waste code: 18 01 08* in accordance with 2000/532/EC); collect and dispose of waste separately.

¹⁾: Personal Protective Equipment; ²⁾: Carcinogenic; Mutagenic; toxic to Reproduction; ³⁾: Depends on used chemical/CMR drug.



Types

Size	S	M	L	
Dimensions [cm]				
Blue gown with knitted cuffs				
Item no.	Unsterile	BI-6700	BI-6800	BI-6900
	Sterile	BI-6701	BI-6801	BI-6901
Light blue gown with elasticated cuffs				
Item no.	Unsterile	-	BI-6500	BI-6550
	Sterile	-	BI-6600	BI-6650
Material Properties				
Material	Spun polypropylene			
Material weight	42 g/m ²			
Liquid-tight coating	Polyethylene			
Coating thickness	approx. 25 µm			
Total weight of gown	120-141 g			

Protection from Mechanical Hazards

Mechanical Properties of Material:

Requirement	Performance Level	
Abrasion resistance (1-6)	2	
Puncture resistance (1-5)	1	
Seam resistance (1-5)	2	
Tear propagation resistance (1-5)	Longitudinal	Transverse
	2	3



Sterilisation

Procedure

Fumigation with ethylene oxide



Protection from Chemical Hazards

Permeation¹⁾ tested in accordance with EN 374 Part 3 (04/94).
 Breakthrough times²⁾ [min] / performance classes³⁾ (1-6) were established for the following chemicals:

Chemical	Breakthrough Time [min]	Performance Class
Carmustine	> 140	4
Amsacrin	> 480	6
Cisplatin	> 480	6
Cyclophosphamide	> 480	6
Doxorubicin	> 480	6
5-Fluorouracil	> 480	6
Methotrexate	> 480	6
Paclitaxel	> 480	6
Thiotepa	> 480	6
Vincristin	> 480	6
30% NaOH	> 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.



Proper Use

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



<p>CE 0299</p>	<p>CE Mark</p>
<p>CE mark for complex PPE in category III in accordance with PPE Directive 89/686/EEC. The type test performed was based on</p> <ul style="list-style-type: none"> • DIN EN 467 (01.99) • DIN EN 374 part 3 (04.94) • DIN EN 340 (03.04) <p>Documented by EC type test certificate no. 04050004. Quality assurance (EC quality assurance system with monitoring): Control measures (usually once a year) by intermediary notified body BG-PRÜFZERT (0299) in accordance with Art. 11B, 89/686/EEC.</p>	
	<p>Notified Body "0299"</p>
<p>Technical Committee for Personal Protective Equipment Testing and certification body of BG-PRÜFZERT Centre for Safety Technology Klinkerweg 4 40699 Erkrath Germany</p>	
	<p>Quality Management System</p>
<p>Our quality management system is tested and certified by TÜV Product Service GmbH (a certification body accredited by the German Accreditation Council,) in accordance with DIN EN ISO 9001:2000. Regular audits and production site inspections guarantee the quality of our products.</p>	
	<p>Storage and Transport Conditions</p>
<ul style="list-style-type: none"> • Dark (protect from direct UV light and sunlight) • Cool (+5 to +40°C) • Dry • No contact with pointed and/or sharp objects 	
	<p>Shelf Life</p>
<ul style="list-style-type: none"> • Unsterile version: 5 years from the date of manufacture • Sterile version: 4 years from the date of sterilisation 	