





**Protective overshoes for use with
cytostatic and biological substances**



Area of application and features

- **Maximum protection and comfort:** Type-tested and certified as complex PPE¹⁾ (category III); chemical protective clothing type PB [4], protective clothing against infection type PB [4]-B; partial body protection. Optimal personal and product protection (sterile version); elasticated cuffs at the leg ends; comfortable to wear; material is latex-free, low in lint with low particle generation; sterile and unsterile version.
- **Area of application:** Protective overshoe for handling CMR²⁾ drugs (e.g. cytostatic and virustatic agents) and biological agents³⁾ (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 exposure 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 hours⁴⁾; 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 supervision⁵⁾ (waste code: 18 01 08⁶⁾ or 18 01 03⁷⁾* 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 as a hazardous waste pursuant to Article 1(4), first indent, of Directive 91/689/EEC on hazardous waste.

⁶⁾: Zytotoxic and zytostatic drugs.

⁷⁾: Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.



Types

Size				Universal
Item-no.	sterile	PU	30	12 55 02
Item-no.	unsterile		40	12 55 01
Colour				Blue/White

Material properties

Material	Spun polypropylene
Material properties	Latex-free
Material weight	42 g/m ²
Liquid-tight coating	Polyethylene
Coating thickness	approx. 25 µm
Total weight of overshoe (pair)	30 g ± 5 g



Protection from mechanical hazards

Mechanical properties of material tested in accordance to EN 14325:2004.

Requirements	Performance level	
Abrasion resistance (1-6) acc. EN 530	2	
Puncture resistance (1-5) acc. EN 863	1	
Seam resistance (1-5) acc. ISO 13935-2	2	
Flex cracking (1-6) acc. ISO 7854	3	
Trapezoidal tear strength (1-5) acc. ISO 9073-4	Longitudinal	Transverse
	3	4

Anti-slip property:

The resistance to slipping of sole was tested in accordance to DIN 4843-100:1993.
Overshoes are appropriate for the designated range of use.



Protection from chemical hazards

Permeation¹⁾ tested in accordance with EN 374:2003.





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
NaOH 30%	> 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
Penetration¹⁾ tested in accordance with EN 14126:2003.	
Resistance to penetration of pathogens, which are blood transmitted using the virus Phi-X174 in accordance with ISO 16604:2004:	
Hydrostatic pressure, for which the material passes the test	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 CFU³⁾)	Performance class (1-3)²⁾
log of the CFU > 1	3
<p>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</p>	
	Sterilisation
Procedure	
Fumigation with ethylene oxide	
	Care instructions
<ul style="list-style-type: none"> ▪ Do not wash ▪ Do not iron ▪ Do not tumble dry ▪ Do not dry clean 	
	CE mark
<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 14605:2005 ▪ DIN EN 14126:2003 ▪ DIN EN 340:2004 <p>Documented by EC type test certificate no. 08050062 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>	



Notified body "0299"

Technical Committee for Personal Protective Equipment
Testing and certification body of
BG-PRÜFZERT
Zwengenberger Strasse 68
D-42781 Haan
Germany



Quality management system

Our **quality management system** is **tested and certified** by TÜV Management 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.



Storage and transport conditions

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



Shelf life

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