Protective sleeve cover for use with cytostatic and biological substances

Area of application and features

- **Maximum protection and comfort:** Type-tested and certified as complex PPE[1)] (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); impervious to liquids in the coated arm region; knitted bands or elasticated at the cuff ends; tapered for comfort; material is latex-free, low in lint with low particle generation; sterile and unsterile version.
- **Area of application:** Protective sleeve cover for handling CMR[2)] drugs (e.g. cytostatic and virustatic 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 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[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 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**
Dimensions [cm]		
Blue sleeve covers with knitted cuff		
Item No.	**Unsterile**	BI-6000
	Sterile	BI-6001
Light blue sleeve covers with elasticated cuff		
Item No.	**Unsterile**	BI-6200
	Sterile	BI-6300

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Material

Material	Spun polypropylene fleece
Material properties	Latex-free
Material weight	42 g/m²
Liquid-tight-coating	Polyethylene
Coating thickness	Ca. 25 µm
Total weight of sleeve covers	20-36 g

Protection from mechanical hazards

Mechanical properties of material tested in accordance with EN 14325:2005.

Requirements	**Performance class**	
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

Protection from chemical hazards

Permeation[1)] tested in accordance with EN 374-3:2003.
Breakthrough times[2)] [min] / performance classes[3)] (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.

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Protection from infectious agents

Penetration[1] 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 CFU[3])	Performance class (1-3)[2]
log of the 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 mark

CE mark for **complex PPE in category III** in accordance with **PPE Directive 89/686/EEC**.
The **type test** performed was based on

- DIN EN 14605:2005
- DIN EN 14126:2003
- DIN EN 340:2004

Documented by **EC type test certificate** no. 08050061.
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.

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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

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