

# PRODUCT INFORMATION

## Isolator protective sleeves

For cytostatics and biological agents

### Application and properties

- + **Maximum protection und comfort:** Type-tested and certified as complex PPE category III; type 6, Chemical protective clothing type PB [6]-B, partial body protection. Optimum personal and product protection; impermeable to liquids, comfortable to wear; elasticated cuffs; sterile version.
- + **Application range:** Protective sleeve covers for working with an isolator glove box. The protective sleeves are worn inside the isolator over the standard isolator protective sleeves. Their purpose is to protect these isolator sleeve covers from CMR medical drugs<sup>1)</sup>. Suitable for liquids or aerosols (type 6), limited protection against liquid chemicals.
- + **Protective barrier:** Liquid impermeable coating.
- + **Protective properties:** Protection against all CMR drugs or chemicals cannot be guaranteed! In case of exposure to biological agents or chemicals, which do not correspond to the degree of imperviousness of the protective clothing, the isolator sleeve covers may be contaminated.
- + **Change interval:** Daily, i.e. use up to a maximum of 8h<sup>2)</sup>; in case of obvious contamination change immediately! Single use!
- + **Before use:** Check for any damage! Do not use damaged isolator sleeve covers!
- + **Waste disposal:** Waste requiring supervision (waste code: 18 01 04 acc. to 2000/532/EC), in case of heavy contamination waste requiring special supervision<sup>3)</sup> (waste code: 18 01 08\* or AS 18 02 07\*, acc. to 2000/532/EC 18 01 08\*<sup>4)</sup>); collect and dispose of separately!

1): Carcinogenic Mutagenic Reproductive Toxic. 2): Dependent on chemicals/CMR drugs used. 3): Waste types marked with (\*) in the waste list are hazardous wastes in the sense of § 41 of the KrW-/AbfG. 4): Cytotoxic and cytostatic drugs.

### Versions

|                             |   |
|-----------------------------|---|
| Size                        | Universal                                     |
| Dimensions                  | Length: ca. 66 cm<br>Diameter: 28 cm or 12 cm |
| Item No. (sterile) 15 pairs | 6451  |
| Colour                      | white   |

### Material properties

|                                    |                                    |
|------------------------------------|------------------------------------|
| Material                           | Spun bonded polypropylene nonwoven |
| Material weight                    | 69 g/m <sup>2</sup>                |
| Material properties                | latexfree                          |
| Liquid-tight coating               | Microporous polyethylene           |
| Total weight of over boots (pairs) | 64 g                               |
| pH-value                           | 9,4                                |

## Protection against mechanical properties

Mechanical properties of material tested in accordance with DIN EN 14325:2004:

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

## Protection against chemical hazards

Permeation tested in accordance with DIN EN 14325 Abs. 4.12 bzw. DIN EN ISO 6530:2005-05

| Chemical              | Breakthrough time | Resistance |
|-----------------------|-------------------|------------|
| Sulphuric acid, 30%   | 3/3               | 3/3        |
| Sodium hydroxide, 10% | 3/3               | 3/3        |
| O-xylene              | 3/3               | 2/3        |
| 1-Butanol             | 3/3               | 3/3        |

**Permeation**<sup>1)</sup> tested in accordance to the European standard EN 374-3:2003 / EN 16523-1:2015. For the following chemicals the breakthrough times<sup>2)</sup> [min] / performance categories<sup>3)</sup> (1-6) were determined:

| Tested chemicals              | Breakthrough time [min] | Performance class |
|-------------------------------|-------------------------|-------------------|
| Carmustine 3,3 mg/ml          | > 480 min               | 6                 |
| Cisplatin                     | > 120 min               | 4                 |
| Cyclophosphamide, 20 mg/ml    | > 120 min               | 4                 |
| 3,3 Diaminobenzidine, 1 mg/ml | > 30 min                | 2                 |
| Etoposide 20 mg/ml            | > 480 min               | 6                 |
| Formaldehyde, 37 %            | > 120 min               | 4                 |
| 5-Fluorouracile, 10 mg/ml     | > 120 min               | 4                 |
| Gemcitabine 38mg/ml           | > 240 min               | 5                 |
| Isopropanol, 70 %             | > 30 min                | 2                 |
| Congo- red, 1 %               | > 30 min                | 2                 |
| Sodium hydroxide, 10 %        | > 120 min               | 4                 |
| Paclitaxel                    | > 120 min               | 4                 |

|                       |           |   |
|-----------------------|-----------|---|
| Sulphuric acid, 30 %  | > 60 min  | 3 |
| Thiotepa              | > 120 min | 4 |
| Vincristine, 20 mg/ml | > 120 min | 4 |

1): Movement of a chemical through a material on a molecular level.

2): At a permeation rate of 1 µg/min.cm<sup>2</sup>

3): The performance class does not reflect the actual duration of protection at the workstation, as temperature and abrasion may have an effect on these!

## Protection from infectious agents

**Penetration<sup>1)</sup>** 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) <sup>2)</sup> |
|----------------------------|---------------------------------------|
| 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) <sup>2)</sup> |
|----------------------------|---------------------------------------|
| 20 kPa                     | 6                                     |

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

| Breakthrough time [min] | Performance class (1-6) <sup>2)</sup> |
|-------------------------|---------------------------------------|
| t > 75                  | 6                                     |

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

| Penetration ration (log) | Performance class (1-3) <sup>2)</sup> |
|--------------------------|---------------------------------------|
| log > 5                  | 3                                     |

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

| Penetration ration (log of CFU <sup>3)</sup> ) | Performance class (1-3) <sup>2)</sup> |
|--|---------------------------------------|
| 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

## Sterilization

Procedure Fumigation with ethylene oxide

## Care instructions

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

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## CE-marking

In accordance to the PPE regulation EU 2016/425 for complex PPE category III; type tested on the basis of DIN EN 13688:2013, EN 13034:2005+A1:2009 and EN 14325:2004. EC-type test and control measures by the notified body „0624“. Documented by EC type test certificate no. CE 1002220676-00-00.

The EC-declaration of conformance and the EC-Type test certificate can be downloaded at [www.berner-safety.de](http://www.berner-safety.de).

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## Notified body „0624“

Centrocot Tessile Contoiere e Abbigliamento S.p.A., Piazza S. Anna 2, 21052 Busto Arsizio (VA), Italien

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## 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.

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## Storage and transport conditions

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

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## Shelf life

- + Non-sterile version: 5 years from the date of manufacture
- + Sterile version: 5 years from the date of sterilization

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## Manufacturer

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

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