

Protective Gloves for Use with Cytostatic Agents



Area of Application and Features

- **Maximum protection and comfort:** type tested and certified as complex PPE¹⁾ (category III); anatomically shaped; extra long, rolled cuff; good grip; good tactile sensitivity; AQL²⁾ = 1,0
- **Area of application:** protective gloves for handling CMR³⁾ drugs (e.g. cytostatic and virustatic agents) and micro-organisms
- **Protection capacity:** protection from all CMR drugs or chemicals is not guaranteed.
- **Glove replacement interval:** every 30 minutes (in accordance with M 620 of the BGW, the German employers' liability insurance association for health and welfare services); after every batch when handling carmustine or thiotepa; immediately in the event of visible contamination. Do not reuse!
- **Protective glove material:** natural latex (latex allergen < 0.5 µg/g); low protein (protein = 17 µg/g); powder free in accordance with TRGS 540; latex and carbamates can trigger allergies.
- **Before use:** check for damage. Do not use damaged gloves.
- **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⁾: Acceptable Quality Level

³⁾: Carcinogenic; Mutagenic; toxic to Reproduction

Types

Size		S or 6½	SM or 7	M or 7½	ML or 8	L or 8½	XL or 9
Item no.	Unsterile	BI-4010	BI-4015	BI-4020	BI-4025	BI-4030	BI-4040
	Sterile	BI-4011	BI-4016	BI-4021	BI-4026	BI-4031	BI-4041

Material Thickness

Measuring Points	Material Thickness d (measured double)
Finger, 15 mm from the end of the tip	≥ 0.91 mm
Middle of the palm	≥ 0.78 mm
Shaft, 25 mm from the end of the shaft	≥ 0.52 mm



Protection from Mechanical Hazards

Mechanical hazards tested in accordance with EN 388 (10/94). Performance level¹⁾ coding as follows:

Requirement	Performance Level
Abrasion resistance (1-4)	1
Cut resistance (1-5)	0
Tear propagation resistance (1-4)	X
Stab resistance (1-4)	X

¹⁾: If the value is less than 1, the result should be given as "0". "X" means that the test could not be performed.





Protection from Chemical Hazards

Permeation¹⁾ tested for numerous chemicals 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
Bleomycins	> 180	4
Carboplatin	> 180	4
Carmustine	> 60	3
Isopropanol/carmustine	> 30 / > 120	2 / 4
Cisplatin	> 180	4
Cyclophosphamide monohydrate	> 120	4
Doxorubicin hydrochloride	> 180	4
Daunorubicin hydrochloride	> 60	3
5-fluorouracil	> 180	4
Methotrexates	> 180	4
Mitomycin	> 180	4
Vinblastines	> 180	4
Vincristines	> 180	4
40% sulphuric acid	> 480	6
96% sulphuric acid	> 10	1
10% sodium hydroxide	> 480	6
40% sodium hydroxide	> 480	6
5% Glutaraldehyde	> 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.



Protection from Bacteriological Hazards

Penetration¹⁾ requirements met in accordance with EN 374 Part 2 (04/94). Test results as follows:

Feature	Evident?
Tears (visual)	No
Cracks (visual)	No
Holes (visual)	No
Air bubbles (air leakage test)	No

In accordance with current knowledge, it should be assumed that meeting the penetration requirements provides effective protection from microbiological hazards (Paragraph 1 of EN 374, Part 2 and Paragraph 3.2 of EN 374, Part 1).





1): Movement of a chemical and/or micro-organism through a porous material on a non-molecular level.



Sterilisation

Procedure	Radiation Dose D per Sterilisation Process
Gamma irradiation	≥ 25 kGy



<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 374 Parts 1-3 • ASTM D3577 • DIN EN 388 • DIN EN 420 • DIN EN 455 Part 1-3 <p>Documented by EC type test certificate no. 97050073. 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 Zwengenberger Strasse 68 D-42781 Haan 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 • Away from equipment or installations that can produce ozone (e.g. through mercury vapour lamps, high voltage equipment, etc.) • Avoid direct contact with metals, such as copper, magnesium and iron • Avoid contact with oil-based antiseptic phenols and their derivatives, fats, petrolatum, petroleum, paraffin or other similar compounds • No contact with pointed and/or sharp objects 	
	<p>Shelf Life</p>
<ul style="list-style-type: none"> • 3 years from the date of manufacture 	