

# PRODUCT BROCHURE

Personal protective equipment and consumables

berner

# Legal foundations

The reason behind the comprehensive range of standards and laws on the subject of personal protective equipment (PPE) is the safety of the user. PPE is divided into 3 categories:

# CATEGORISATION AND DIFFFERENCES OF PPE IN ACCORDANCE WITH THE EU REGULATION 2016/425 (PREVIOUSLY 89/686/EEC A TRANSITIONAL PERIOD APPLIES UNTIL 21 APRIL 2018)

Category	1	Ш	III
Protection	against minimal risks	against medium risks	against deadly hazards or serious irreversible damage to health
EC- Quality assurance	-	-	<b>✓</b>
EC- Type testing	-	<b>~</b>	<b>✓</b>
Category	CE	CE	CE + identifcation no. <sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Number of notified body: http://europa.eu.int

The necessary PPE category for each case is determined as part of a risk analysis. For chemicals, CMR pharmaceuticals and biological agents it is the highest category IIII.

#### PPE-USER REGULATIONS

The German PPE user regulations (PSA-BV) is a German regulation of the EU regulation 2016/425.

- §1 The law regulates the supply of personal protective equipment (PPE) by the employer as well as stating their use by the employees.
- §2 describes the basic requirements which the employer has to adhere to for the acquisition, maintenance and storage of the PPE.
- §3 contains information on how to instruct and train the employees in the use of PPE.

Iln Europe all PPE which is brought into circulation has to be tested to the harmonised European EN standards. Tests based on the American ASTM standards are not permissible according to European law. The adherence to the specific standards is intended to provide safety for the user. Values such as permeation times (for chemicals – break-through times on a molecular level) can only be compared if they were all tested to the same standard.

#### LEGAL PROVISIONS WITHIN THE EU

- 4. EU-regulation 2016/425 (previously 89/686/EEC)
- General EN standards for specific PPE

   (e.g. EN 340 for protective clothing, EN 420 for protective gloves)
- 6. Test standards for specific applications (z.B. EN 374 part 1, 2, 4 and 5 as well as EN 16523-1 for chemical protective gloves)
- **7. Implementation into national law** (Laws regarding the availability of personal protective equipment on the market )
- 8. PPE- User regulations (eg. PSA-BV in Germany)

# VOLUNTARY, ADDITIONAL TESTS WHICH ARE NOT OBLIGATORY



Tests to the American standard ASTM (e.g. ASTM F 1671, ASTM D 6978-05, ...)

#### OVERVIEW OF LEGAL FOUNDATIONS

Important European standards for: Protective clothing (Type 3, 4, 5 and 6 only) against chemical and infectious agents

# Standards

• EN ISO 13688 – Protective clothing - general requirements

Legal

- EN 14126 Performance requirements and tests methods for protective clothing against infective agents
- EN 14325 Protective clothing against chemicals Test methods and performance classification of materials, seams, joins and assemblages
- EN 14605 Protective clothing against liquid chemicals Performance requirements for clothing with liquid-tight (type 3) or spray-tight (type 4) connections
- EN ISO 6529 Protective clothing Protection against chemicals Determination of resistance of protective clothing materials to permeation by liquids and gases
- EN ISO 6530 Protective clothing Protection against liquid chemicals -Test method for resistance of materials to penetration by liquids
- EN ISO 17491-3 Protective clothing Test methods for clothing providing protection against chemicals Part 3: Determination of resistance to penetration by a jet of liquid (jet test)
- EN ISO 17491-4 Protective clothing Test methods for clothing providing protection against chemicals Part 4: Determination of resistance to penetration by a spray of liquid (spray test)
- EN ISO 13982 Parts 1+2 Protective clothing for use against solid
  particulates Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid
  particulates, Part 2: Test method of determination of inward leakage of
  aerosols of fine particles into suits
- EN 13034: Protective clothing against liquid chemicals Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 & Type PB [6] equipment)
- EN 13921 Personal protective equipment Ergonomic principles
- EN ISO 16604 -Clothing for protection against contact with blood and body fluids. Determination of resistance of protecive clothing materials to penetration by blood-borne pathogens. Test method using Phi-X 174 bacteriophage

#### Protective gloves against chemicals and infective agents

- EN 420 Protective gloves General requirements and test methods
- EN 374-1 Protective gloves against chemicals and micro-organisms Part 1: Terminology and performance requirements
- EN 374-2 Protective gloves against chemicals and micro-organisms Part
   2: Determination of resistance to penetration (Breakthrough due to micro holes)
- EN 16523-1 Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
- EN 374-4 Protective gloves against chemicals and micro-organisms -Part 4: determination of the resistance against degradation by chemicals
- EN 388 Protective gloves against mechanical risks
- EN ISO 374-5 Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks

#### Eye protection

• EN 166 – Personal eye protection - requirements

#### Particle filtering masks

- EN 149 Respiratory protective devices Filtering half masks to protect against particles - requirements, testing, marking
- EN 136 Respiratory protective devices Full face masks requirements, testing, marking

# Contents

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# Protective gloves

The right glove should not just fit – it should also be easy to change and above all, provide reliable protection against hazardous substances. In accordance with the relevant regulations in the EU, the employer is required to provide his employees with suitable protective gloves of the correct category when handling dangerous materials. Berner International offers certified gloves of premium quality – safe and comfortable. Therefore you should pay attention to the quality of your personal protective equipment.

Your safety is at stake.

You would like further details?
To access more information using your smartphone or tablet www.berner-safety.de/gloves



#### COMPLETE DOCUMENTATION

For the GMP-compliant manufacturing of e.g. cytotoxic drugs sterile single use protective gloves which are suitable for cleanroom use are an absolute must. On request Berner International can automatically send you the appropriate sterility certificates for every batch.

# PROTECTION AGAINST CHEMICALS AND CMR DRUGS

Permeation tests were carried out in Europe in line with the directive 89/686 / EEC (PPE) for many years in accordance to EN 374-3. In 2015, the EN 374-3 standard was replaced by standards EN 16523-1 and EN 16523-2. A new version of EN 374-1 came into the market in 2017, which also has an effect on the permeation tests. Why is this important? The standardised European standards form the standard and should ensure comparability of the protection function for you as a user. However, there are always products on the market which have been tested either according to the American standard ASTM F 739 or ASTM D 6978, or only to the directive for medical gloves (EN 455). Whether these gloves provide protection against hazardous substances must be examined in each individual case; legally the European standards are binding.

# PROTECTION AGAINST VIRUSES AND BIOLOGICAL AGENTS

Penetration tests (breakthrough through microholes) are tested throughout the EU in accordance to EN 374-2. Unfortunately the test to EN 374-2 does not include a virus test. For this reason, Berner International always makes sure that all protective gloves are additionally tested to the American standard ASTM F 1671. There is now a new standard, EN 374-5. This additional European standard for protective gloves against dangerous chemicals and microorganisms also contains a viral protection test like ISO 16604 which is similar to the ASTM F 1671 test.

# Expert knowledge - glove materials MATERIALS FOR SINGLE USE GLOVES

#### **LATEX**

Latex has been **the** material for disposable gloves, for medical as well as protective gloves. In the fifteenth century Spanish conquerer brought natural latex from South America to Europe. For a long time no one saw the great potential in the juice of the rubber tree Hevea brasiliensis, until Charles Goodyear in 1839 developed vulcanization by chance. Since 1890 examination gloves made of latex have been used in medicine. The material is elastic, comfortable to wear and resistant to chemicals- but unfortunately causes allergies in about 1% of the



The latex allergy (allergy type I = immediate type), which became known in the 1990s, is primarily due to latex proteins. It has been reinforced with the use of powdered gloves. The powder in the form of corn starch particles prevented the gluing together of gloves and ensured easy donning and doffing.

During the handling of the gloves, the powder and thus the latex proteins passed through the air into the mucous membranes and the respiratory tract. The allergic reaction usually occurs within a few seconds to 30 minutes.

According to TRGS 401: To protect against this allergy, no powdered latex gloves may be used for many years. Furthermore, the protein content in latex gloves can be significantly reduced by complex, technical washing processes. A latex glove is considered to be low in protein when it contains no more than 30 mg of latex proteins per g of glove material.

A second type of allergy is the type IV allergy (= late type). The user reacts allergic to manufacturing by-products such as mercaptobenzothiazole (MBT), thiurame or carbamate. High-quality latex or neoprene gloves only contain carbamates whose allergic potential is the lowest. These accompanying substances are also reduced by complex processes down to the detection limits. Allergic reactions of this type often do not occur until about 6-8 hours sometimes not until 72 hours.

The third type of allergy is the so-called pseudo-latex allergy. In this case, the user reacts to the dampwarm environment, while wearing a glove. This type of allergy is independent of the latex material and occurs in other materials such as neoprene or nitrile.

Despite the allergy problem, latex protective gloves are still very popular today. The reason for this is especially the wearing comfort and the good protection against certain chemicals (for example, acids and alkalis, but also many cytostatics) contribute to this success. However, latex gloves should not be the first choice for handling oils and solvents.

# Mio

#### **NEOPRENE**

Polychloroprene is a high-quality synthetic rubber, which was manufactured by Arnold Collins for the first time in an economical emulsion process. The material, also known under the brand name neoprene, is used for a variety of applications. In addition to protective gloves and the basis for adhesives, the vulcanized variety has become known as a diving and swimming suit.

Protective gloves made of neoprene are 100% latex-free and are an alternative for people who are allergic to latex an alternative with similar comfort. Depending on the composition of the material, protective gloves made of polychloroprene provide relatively good protection against organic solvents, many cytotatics and standard chemicals.

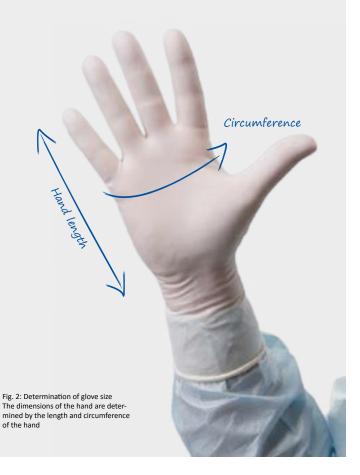
#### **Further materials**

Polyisoprene is a relatively new and currently very expensive material. The latex material is almost molecularly accurate and therefore has the same good stretching and wearing properties. At the same time, however, it is free of allergenic substances.

Vinyl actually means the material polyvinyl-chloride (PVC) and is an inexpensive glove material which, however, has only low mechanical strength and low protection against biological agents. Chemical resistance is limited. For the production of vinyl gloves, plasticizers (phthalic esters in various forms) are added. These are fat-soluble and can be easily absorbed through the skin and accumulated in the body when they come into contact with greasy or oily substances.

#### **NITRILE**

Nitrile rubber, actually acrylonitrile-butadiene rubber, consists of acrylonitrile and 1,3-butadiene. The material was developed in 1930 by the I.G. Colors has evolved and is now one of the most important glove materials. The good resistance of nitrile against oils, fuels, solvents and many cytostatics is very dependent on the mixing ratio between acrylonitrile and 1,3 butadiene. For this reason the permeation lists of nitrile protective gloves should always be studied carefully.



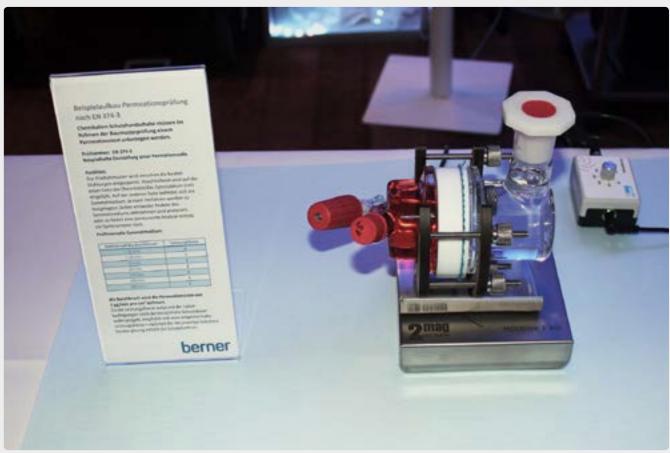


Fig. 3: An example of a test cell

# How do medical gloves differ from protective gloves?

Medical gloves are primarily used for hygiene and to avoid infections during the doctor-patient contact. This type of disposable gloves are tested according to EN standard 455 (single use medical gloves). These include a leak test, an examination of the physical properties, a biological evaluation of the gloves (protein content, endotoxin content, ...) and minimum requirements. Chemical protection gloves, on the other hand, are intended to protect the user from hazardous chemicals. For this reason, protective gloves are subjected to a series of stringent standard tests.

#### **Basics for testing protective gloves**

Protective gloves must first meet the requirements of EN 420 (protective gloves). This standard describes the requirements for all types of protective gloves (e.g. protective gloves for forest workers) and covers the harmlessness of protective gloves, minimum sizes (depending on the size of the glove), different performance levels for dexterity. The detailed print is obligatory to prevent any confusion.



#### Penetration testing of chemical protective gloves

Chemical protective gloves must continue to comply with the EN 374 standard (protective gloves against chemicals and micro-organisms). In the penetration test in Part 2, the glove is examined by filling with air or water on micro-holes.

The result of this test is reflected as an AQL value (AQL = Acceptable Quality Level). In general, for AQL: the smaller the value, the better the quality of the glove. However, the values of the water test cannot be compared with the results of the air test.

#### Permeation testing of protective gloves

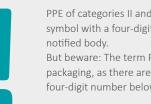
During the permeation test (penetration of chemicals at the molecular level) according to EN 374-1 and EN 16523-1 (formerly EN 374-3), the time is measured until a precisely defined minute quantity of the test chemical has penetrated the glove material. Here, according to the new standard, there are three different types of protective gloves. A selection of 18 standard chemicals is available for the test. If at least 6 of these substances pass the test for at least 30 minutes, it is declared as type A. If the protective glove holds only 3 substances for at least 30 minutes, it is a type B. Protective gloves which retain only one substance for at least 10 minutes are referred to as type C. All tested chemical protective gloves are marked with the symbol of the Erlenmeyer flask and the specification of the respective type. The beaker icon will not be used in the future.

#### Mechanical risks

Furthermore, protective gloves according to EN 388 (protective gloves against mechanical risks) are still tested for abrasion resistance, cutting strength, tear strength and puncture force. Only after all these examinations have been successfully passed, the glove may be called "protective glove against chemicals and microorganisms".

# Protective gloves and category III personal protective equipment

In the case of protective gloves sold as part of a "personal protective equipment of category III", all tests, documentation and the product itself has to be tested by an official certification body (known as "Notified Body". In addition, the manufacturer must have a quality management system (monitored in accordance with Article 11B of the PPE directive) or a continuous quality assurance for the final product in accordance with Article 11A of the PPE directive with appropriate controls. It is only when this last test has been successfully passed that the protective glove receives the certificate for "personal protective equipment of category III"- the highest level for your personal safety.



PPE of categories II and III are recognizable by the CE symbol with a four-digit number. The number of the notified body.

But beware: The term PPE must also be on the packaging, as there are also medical products with a four-digit number below the CE mark.



## Dermagrip Ultra LT\*

Protective glove with innovative SafeDon-dispensing system

Short nitrile protective glove for working in non-sterile areas (e.g. preparatory work in the cytostatic laboratory, biology laboratory, oncology ward, veterinary practice, etc.). With the new SafeDon dispenser system contaminations have been shown to be greatly reduced. At the same time the size of the packaging has been reduced. Available as a 200 dispenser box (suitable dispensing system available) or 50 dispenser box for mobile applications.

Permeation list: Tested for various substances.

Detailed information available at www.berner-safety.de/safedon\_gb

#### **Certified safety**

- + AQL = 1.5 (water test)
- + Additionally tested as medical gloves according to 93/42/EEC (CE class 1) EN 455.

#### Material

- + Special nitrile mix
- + Non-sterile
- + No detectable allergens
- + Especially resistant against many chemicals

#### **To order** Dermagrip Ultra LT – Colour blue

	- (-)			
Size	S (6)	M (7)	L (8)	XL (9)
Order No. (200 box)	100176	100177	100178	100179
Order No. (8 x 50 box)	5011	5016	5021	5026



#### Manu N

Nitrile protective glove - the marathon glove

N stands for nitrile, a synthetic copolymer with a special composition. To guarantee the highest level of protection of nitrile protective gloves, many years of experience and various permeation tests have been necessary. The Berner protective glove Manu N sets new standards when handling chemicals, CMR drugs (e.g.cytostatics) and biological agents.

A comprehensive permeation list: Tested for numerous substances. Detailed information available at www.berner-safety.de/manu\_n\_gb

#### **Certified safety**

- + AQL = 1.5 (water test)
- + Ideal for e.g. the GMP-compliant production of cytostatics
- + Suitable for cleanrooms up to ISO class 5 to EN ISO 14644-1:1999
- + Sterile poly/poly bag packaging
- + Viral protection in accordance to ASTM F 1671

#### Material

- + Special nitrile mixture
- + Sterile and non-sterile
- + No detectable allergens
- + High resistance to many chemicals
- + Extra long: 300 mm
- + 15 cytostatics tested
- + Special stainless steel dispensing system available

#### **To order** Manu N – Colour light blue

Size	XS (6)	S (7)	M (8)	L (9)	XL (10)
Order No. (non-sterile)	3010	3015	3020	3025	3030
Order No. (sterile)	3011	3016	3021	3026	3031



#### Manu Prene XP

Latex-free neoprene glove - not just for allergy sufferers

Neoprene protective gloves made from especially high quality polychloroprene and protect the user from CMR substances e.g. cytostatics, various chemicals, biological agents and viruses. Due to the material composition these gloves are to be particularly recommended for existing latex allergies.

Comprehensive permeation list: Tested for numerous substances.

Detailed information available at www.berner-safety.de/manuprene\_gb

#### **Certified safety**

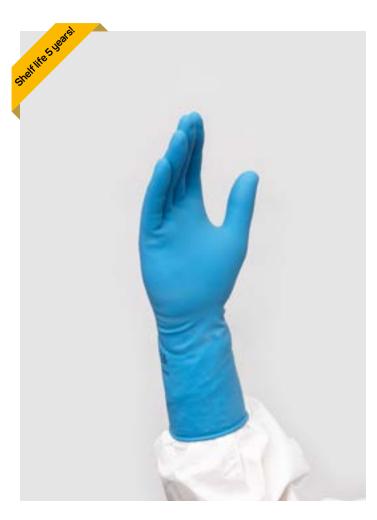
- + AQL = 1.0 (water test)
- + Ideal for e.g. the GMP-compliant production of cytostatics
- + Suitable for cleanrooms up to ISO class 5 to EN ISO 14644-1:1999
- + sterile plastic packaging
- + Viral protection in accordance to ASTM F 1671
- + Additionally tested as medical gloves in accordance to EN 455

#### Material

- + 5 year shelf life
- + Sterile and non-sterile
- + No detectable allergens
- + Polymer-coating for easy donning and removal
- + Anatomical shape
- + Length: 295 mm
- + Special stainless steel dispenser system available

#### To order Manu Prene XP – Colour latte machiato

Size	XS (6)	S (6 ½)	SM (7)	M (7 ½)	ML (8)	L (8 ½)	XL (9)
Order No.(non-sterile)	2010	2012	2014	2016	2018	2020	2022
Order No. (sterile)	2011	2013	2015	2017	2019	2021	2023



#### Manu L

Latex protective glove - the robust standard

L stands for "Latex", a natural product, which is made from the sap of the rubber tree. The protective gloves' distinguishing features are their special elasticity, high wearing comfort and extra protective properties for cytostatic substances, many chemicals and biological agents. A special virus protection test provides additional safety.

Comprehensive permeation list: Tested for numerous substances.

Detailed information available at unter www.berner-safety.de/manu | gb

#### **Certified safety**

- + AQL = 1.0 (water test)
- + Ideal for e.g. the GMP-compliant production of cytostatics
- + Suitable for cleanrooms up to ISO class 5 to EN ISO 14644-1:1999
- + sterile polythene packaging
- + Viral protection in accordance to ASTM F 1671
- + Additionally tested as medical gloves in accordance to EN 455

#### Material

- + 5 year shelf life
- + Sterile and non-sterile
- + Powder-free
- + Low in protein: 17  $\mu$ g/g
- + Very low allergenic: 0.5 μg/g
- + Anatomical shape
- + Length: 295 mm
- + High material thickness
- + Special stainless steel dispenser system available

#### **To order** Manu I – Colour blue

Size	S (6½)	SM (7)	M (7½)	ML (8)	L(8½)	XL (9)
Order No. (nsterile)*	4010	4015	4020	4025	4030	4040
Order No. (sterile)**	100207	100208	100209	100210	100211	100212

<sup>\* 50</sup> pairs \*\*200 pairs



#### **Profeel NR**

Latex glove - low material thickness with good protection

Chemical glove with optimised fit for long, fatigue-free working. Due to the low wall thickness the glove also offers good tactile sensitity and is suitable for double-gloving. The inner coating makes it easier to change the gloves, the rolled cuff edge fixes the glove shaft to the coverall or oversleeve. Also suitable for use with isolator rings.

#### **Certified safety**

- + AQL = 0.65 (water test)
- + Optimal for GMP-compliant production of cytostatics
- + Suitable for cleanrooms up to ISO class 5 to EN ISO 14644-1:1999
- + Poly/poly sterile packaging
- + Viral protection in accordance to ASTM F 1671
- + Additionally tested as medical gloves in accordance to EN 455

#### Material

- + Sterile
- + Powder-free
- + Low in protein:  $12 \mu g/g$
- + Very low allergenic: 0.3 μg/g
- + Anatomical shape
- + Length: 290 mm

#### **To order** Profeel NR – Colour vanilla

Size	XS (6)	S (6 ½)	SM (7)	M (7 ½)
Order No. (200 pairs)	100000	100001	100002	100003
Size	ML (8)	L (8 ½)	XL (9)	
Order No. (200 pairs)	100004	100005	100006	



## **Dermagrip-D**

The non-sterile version of the Profeel NR

Chemical protective glove made of latex with optimized anatomical fit for long, fatigue-free working. Due to the low wall thickness, the protective glove offers a good tactile feel. The inner coating facilitates the change of the glove, the roller edge fixes the glove on the protective gauntlet or the protective arm cuff. The protective glove is additionally tested as a medical glove according to EN 455 and also has the virus protection test according to ASTM 51671

#### **Certified safety**

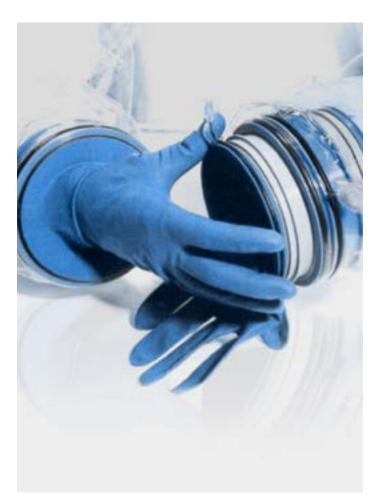
- + AQL = 1.5 (water test)
- + Dispenser box with 25 pairs
- + Viral protection in accordance to ASTM F 1671
- + Additionally tested as medical gloves in accordance to 93/42/ EEC (CE class 1) EN 455

#### Material

- + Sterile
- + Powder-free
- + Low in protein: 12  $\mu g/g$
- + Very low allergenic: 0.3 μg/g
- + Anatomical shape
- + Length: 290 mm

#### **To order** Dermagrip-D – Colour vanilla

Size	XS (6)	S (6 ½)	SM (7)	M (7 ½)
Order No. (25 pairs)	100007	100008	100009	100010
Size	ML (8)	L (8 ½)	XL (9)	



## **Isolator-Glove Changing System**

Changing gloves safely during normal operation

When handling cytostatic substances and CMR drugs, but also chemicals, there are recommendations set out by the German Federal Association for Health and Welfare (BGW), which states that protective gloves should be changed at least every 30 minutes. The reason for this is the breakthrough on a molecular level (permeation), which is the movement of a chemical through the unbroken protective material. The innovative glove changing system makes it easy and safe to keep to the recommended changing times for protective gloves. The complete glove changing system can also be installed at other commerically available isolators and glove boxes. Should you already have a double ring system - our gloves will very likely fit your system, too.

- + Keeping to the recommended glove changing frequency is easily achieved even when working at an isolator
- + Changing gloves safely while in use due to multiple sealing system
- + Cost-effective: Expensive special gloves are unnecessary
- + Perfect protection: Tested and certified protective gloves

#### To order Isolator-glove-changing system

Locking ring	803018	Isolator sleeve covers (vinyl) 803016
Glove inner ring	803021	Dauble and for inner sing 202010
Retaining ring 85 mm	803020	Double seal for inner ring 803019
Retaining ring 300 mm	803015	Sleeve cover isolator* 6451

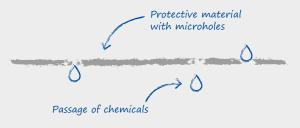
<sup>\*</sup>patented system

# Expert knowledge safety gloves

#### DIFFERENCE BETWEEN PENETRATION AND PERMEATION

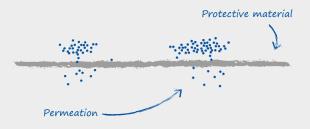
# Penetration is defined as the passage of material through micro-holes!

These can be caused during manufacture, or incorrect packaging or storage.



# Permeation is the passage of substances on a molecular level in undamaged material!

Depending on the protective barrier or chemical this process can take from a few seconds to many hours/days.





#### Ultranitril 492

Thin reusable long-lasting protective glove

Nitrile protective gloves for working in pathology, anatomy, crematories and laboratories. Anatomical shape and flock-lining on the inside makes the gloves comfortable to wear.

Permeation list: Tested for various substances.

Detailed information available at www.berner-safety.de

#### **Certified safety**

- + Personal protective equipment (PPE) of the highest category III
- + Type tested and certified
- + Protection against chemical risks in accordance to EN 374-3-2003
- + Good protection against diluted chemicals
- + Multiple use (please see product information)

#### Material

- + Non-sterile
- + Exterior finish: embossed texture
- + Straight cuff
- + Anatomical shape
- + Interior finish: flock-lining
- + Length: 320 mm

#### **To order** Ultranitril 492 – Colour green

Size	S (6)	SM (7)	M (8)	ML (9)	L(10)	XL (11)
Order No. (non-sterile)*	100029	100030	100031	100032	100033	100034

<sup>\* 20</sup> pairs



## Ultranitril 480

Particularly long chemical protection glove

Chemical protective nitrile protective gloves for long, optimized use. Due to the excellent resistance this glove is also highly resistant to abrasion and perforation. The nitrile glove offers a good grip due to the embossed texture. With its 460 mm cuff the glove reaches up to the elbow. Chlorinated for easy donning and taking off.

Permeation list: Tested for various substances. Detailed information available at www.berner-safety.de

#### **Certified safety**

- + Personal protective equipment (PPE) of the highest category III
- + Type tested and certified
- + Protection against chemical risks in accordance to EN 374-3:2003 and ASTM F 739
- + Multiple use (please see product information)

#### Material

- + Nitrile mixture
- + Non-sterile
- + Straight cuff
- + Anatomical shape
- + Good grip due to embossed texture
- + Length: 460 mm

#### **To order** Ultranitril 480 – Colour green

Size	S (7)	M (8)	ML (9)	L (10)
Order No. (non-sterile)	100025	100026	100027	100028

\* 12 pairs



#### Stansolv AK 22 381

Multi-layer protective glove for reliable protection

The Stansolv AK-22 381 protective glove offers reliable protection against many liquids and chemicals. The combination of the nitrile glove with cotton knit lining for more wearing comfort and theremal insulation. Embossed texture for gripping wet objects.

Comprehensive permeation list: Numerous substances tested. For further information: www.berner-safety.de

#### **Certified safety**

- + Personal protective equipment of the highest category III
- + Excellent protection against concentrated chemicals
- + Type-tested and certified
- + Comprehensive permeation list
- + Multiple use (see product information)

#### Material

- + Non-sterile
- + Nitrile-mixture
- + Exterior finish: embossed texturel
- + Anatomical shape
- + Scalloped cuff
- + Interior finish: cotton-knit lining
- + Length: 355 mm

#### **To order** Stansolv AK-22 381 – Colour green

Size	S (7)	M(8)	ML (9)	L (10)	XL (11)
Order No. (non-sterile*)	100016	100017	100018	100019	100020

<sup>\* 12</sup> pairs



The chemical protective glove Trionic 517 is suitable use in cleanrooms up to ISO Class 5. Consisting of tri-polymer blend of natural latex , neoprene and nitrile, the glove provides increased comfort while protecting optimally against mechanical and chemical risks. The wide cuff supports the doublegloving procedure.



- + Personal protective equipment of the highest category III
- + Very good protection against concentrated chemicals
- + Type-tested and certified
- + Very comprehensive permeation
- + Multiple use (see product information)

#### Material

- + Non-sterile
- + Made of tri-polymer
- + Straight cuff
- + Exterior finish: embossed texture
- + Interior finish: chlorinated
- + Length: 360 mm

#### To order Trionic 517 – Colour yellow

Size	S (7)	M(8)	ML (9)	L (10)	XL (11)
Order No. (non-sterile)*	100035	100036	100037	100038	100039

\* 12 pairs





#### **Butoflex 651**

Butyl-protective glove for handling many different chemicals

The gloves Butoflex 651 offers maximum chemical resistance against highly caustic acids, ketones, esters and amine derivatives. Due to the unique flexibility and dexterity the protective gloves can be used for a wide range of tasks.

#### **Certified safety**

- + Category III personal protective equipment
- + Protection against chemical risks in accordance to EN 374-3-2003 and ASTM F 739
- + Protective gloves with electrostatic properties in accordance to EN 16350
- + Electrostatic properties: <1,0 10E5

#### Material

- + Non-sterile
- + Butyl rubber
- + Rolled cuff edge
- + Palm with profile
- + Anatomical shape
- + Material thickness: 0.5 mm
- + Length: 350 mm

#### **To order** Butoflex 651 – Colour black

Size	S (7)	M (8)	L (9)	XL (10)
Order No. (non-sterile - 6 pairs)	100040	100041	100042	100043



## **Kronit-Proof 395**

Cut-resistant protective glove combined with good chemical protection

The Kronit-Proof 395 protective gloves offer a complete hand protection against cuts (level 5), good protection against thermal risks and is particularly resistant to mechanical stress. Through multi-layer technology, the glove is liquid-tight and facilitates secure handling of wet and slippery objects. Characterized by long-lasting performance: the Kronit-Proof 395 retains its properties unchanged for up to 5 washes.

#### **Certified safety**

- + Personal protective equipment (PPE) of the highest category III
- + Type tested and certified
- + Protection against chemical risks in accordance to EN 374-3-2003 and ASTM F 739
- + Highest cut resistance class 5
- + Electrostatic properties: <1.0
- + Material
- + Non-sterile
- + Nitrile / Cotton-Multi-layer technology
- + Anatomically shaped
- + Straight cuff
- + Interior finish: cotton knit
- + Length: 320 mm

#### **To order** Cut resistant gloves Kronit-Proof 395 – Colour green

Size	M (8)	L (9)	XL (10)
Order No. (non-sterile- 1 pair)	100022	100023	100024

# No.

## **Expert Know-How protective gloves**

# DEGRADATION - THE EFFECT OF MATERIAL CHANGES ON BREAKTHROUGH TIME

# Coming into contact with chemicals can alter or even damage protective gloves.

This change in physical material properties is called degradation. It can vary from differences in colour to hardening or softening up to dissolving the material. Some changes may be reversible, other forms of degradation are, however, irreversible and/or accumulate during the lifetime of the gloves. In both cases the protective functions of the gloves can have a lasting negative effect.



To be able to determine and compare the degradation resistance of protective gloves against chemicals and microorganisms, these are tested in accordance to the standard EN 374-4. Here the puncture resistance of the material is determined

after a defined contact period with the test chemical and compared to the untreated material. The test set-up only takes into account liquid chemicals. Also, the test is only valid for gloves made from natural or synthetic polymers.

Single-use gloves should generally be worn for a short period of time and should only be used once. Therefore the degradation problem normally plays a less important role. The resulting reduction of the protective effect for permeable substances is generally more suitable when carried out as part of the permeation testing procedure (see expert know-how penetration/ permeation).

This is different for reusable chemical protective gloves. The material changes can still be present after cleaning and drying. For this reason reusable glove degradation results have to be given for each tested chemical. These are measured using differences in the puncture resistance (residual force) of the glove material and are given as four levels. Number 1 stands for a low residual force, 4 for a high one.

In addition, visual differences and weight changes (e.g. swelling of the material) have to be specified. The relevant details can be found in the product information for each type of glove.

# Protective coverall & partial protection

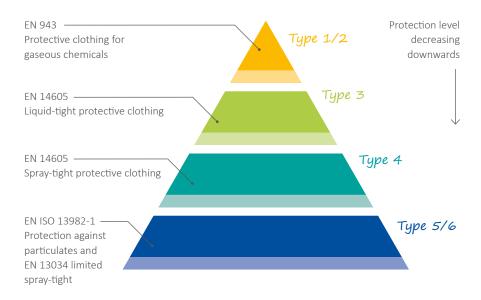
Protective coveralls and partial body protection clothing for the laboratory in Europe, just like gloves, have to comply with the PPE directive 89/686/EEC or PPE regulation 2016/425. Depending on the individual risk assessment suitable protective clothing has to be selected. We would be pleased to advise you to determine the appropriate protective clothing suitable for your specific needs. It's all about your safety.

You want to know more? Simply use your smartphone or tablet to access www.berner-safety.de/ppe



#### PROTECTIVE CLOTHING PYRAMID

The safety pyramid gives an overview of the various protection levels. Within these protection levels different materials and seam finishes offer, in conjuction with the other PPE components, offer protective advantages.



## CATEGORISATION & DIFFERENCES OF PPE IN ACCORDANCE TO EU-DIRECTIVE 89/86/EEC OR PPE REGULATION 2016/425

Category	I	II	III
Protection	against minimal risks	against medium risks	against deadly hazards or serious irreversible damage to health
EC-quality assurance	_	_	<b>✓</b>
EC- type test	_	<b>✓</b>	<b>✓</b>
Marking	CE	CE	CE + Mark <sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Number of the certificated notified body: http://europa.eu.int

The necessary PPE category for each case is determined with the aid of a hazard analysis. For CMR pharmaceuticals, for example, it is the highest category III. This also applies to reusable cleanroom overalls, which are used for handling cytostatics. These also have to be tested to the highest PPE category III and have a corresponding type test certificate. It is always the responsibility of the operator to provide the **right** PSA.



#### **Protective coverall Active Breath II**

Certified breathable personal protection against chemicals

Category III protective coverall offers optimum protection against hazardous substances such as chemicals. However, this is usually at the expense of breathability and wearing comfort. For this reason cleanroom overalls tend to be worn instead. These offer breathability and protection for the cleanroom, but they are not classed as certified personal protection equipment (in accordance to the PPE directive 89/686/EEC or PPE Regulation 2016/425) certified PPE **must** be worn when handling hazardous substances).

The protective coverall BERNER Active Breath Z+B+® unites personal protection and breathability in a unique way. In the vulnerable areas (at the front, shoulder and leg region) the protective coverall contains tested and certified personal protective material. The back part of the coverall is made from breathable material and guarantees a controlled air exchange for maximum comfort.

To order Protective coverall Active Breath II

Size	S	М	L	XL	XXL	XXXL
Chest girth (cm)	84–92	92-100	100-108	108-116	116-124	>124
Body height (cm)	164–170	170–176	176–182	182-188	188–194	>194
Order No. (non-sterile - 8 pcs)	100183	100184	100185	100186	100187	100188
Order No. (sterile - 6 pcs)	100189	100190	100191	100192	100193	100194



## Protective coverall Tyvek® Classic Plus

Type 4/4-B protective coverall against cytostatics, chemicals and biological agents

The type 4 coverall DuPont™ Tyvek® Classic Plus offers good protection when handling cytostatic agents and against many chemicals and biological agents. The well-known Tyvek-material is very robust, extremely comfortable to wear and meets the requirements of EN 1149-1 being anti-statically treated. Suitable for use as a pandemic protective gown (e.g. bird flu, etc.), but not suitable for Ebola or similar viruses.

To order Protective coverall Tyvek® Classic Plus

Size	S	М	L	XL	XXL	XXXL
Chest girth (cm)	84–92	92–100	100-108	108–116	116–124	124-132
Body height (cm)	162-170	168–176	176–182	180-188	186-194	192-200
Order No. (non-sterile - 25 pcs)	100109	125685	125686	125687	125688	100098
Order No. (sterile - 6 pieces)	100110	125680	125681	125682	125683	100097



## Protective coverall Tyvek® 800J

Light type 3/3-B coverall

The Model Tyvek® 800J from DuPont is another type-3 coverall. As light as a type-4 overall, the 800J still provides the same level of protection as a type 3 coverall. Due to the new material, the overalls are more breathable than other type 3 overalls and offer good protection against inorganic chemicals at low concentrations and biological agents.

To order Coverall Tyvek® 800J

Size	М	L	XL	XXL
Chest girth (cm)	92-100	100-108	108-116	116-124
Body height (cm)	170-176	176-182	182-188	188-194
Order No. (non-sterile- 20 pcs)	125661	125663	125665	125667



# Protective coverall Tychem® C

Type 3/3-B: Perfect protection against inorganic chemicals and biological agents

The well-known type-3 protective coverall Tychem® C acts a very effective barrier against many inorganic chemicals. Stitched and overtaped seams, a special chinguard and the robust yellow surface material together with other PPE components (safety goggles, respiratory face mask, etc.) provide the perfect protection for the user. Also for a pandemic task force (e.g. Ebola, etc.) the ideal choice.

To order Coverall Tychem® C

Size	М	L	XL	XXL
Chest girth (cm)	92-100	100-108	108-116	116-124
Body height (cm)	168-176	174-182	180-188	186-194
Order No. (non-sterile - 5 pcs)	125650	125652	125654	125656



## Protective coverall Tychem® F

Type 3/3-B: Protection against infection and many highly concentrated organic and inorganic chemicals

This premium product Tychem F offers even more protection than a Tychem C- coverall and resists pressures up to 5 bar. A particularly extensive permeation list is available for this coverall.

To order Coveralls Tychem® F

Size	S	М	L	XL	XXL	
Chest girth (cm)	84-92	92-100	100-108	108-116	116-124	
Body height (cm)	162-170	168-176	174-182	180-188	186-194	
Order No. (non-sterile - 25 pcs)	on request					



# Tyvek® IsoClean®

Specially cleaned and sterilised protective overall for clean room applications class  $\rm B$  /  $\rm ISO$  class  $\rm 5$ 

The new overall IsoClean is specially cleaned and packed and sterilised under controlled conditions. Tested and certificated protective overall for handling cytostatics. Especially low in particles for use in cleanrooms ISO-class 5 (as per ISO 14644-1) and GMP-class B (GMP-Guidelines Annex 1). Version without hood and boots. Triple poly-packaging for cleanroom use.

To order Protective coverall Tyvek® IsoClean®

Size	S	М	L	XL	XXL
Chest girth (cm)	84-100	92-100	100-108	108-116	116-124
Body height (cm)	162-170	168–176	176–182	180-188	186–194
Order No. (sterile - 6 pieces)	100118	100114	100115	100116	100117



# Coverall Tyvek® Labo

Coverall for laboratories and pharmaceutical industry - Type 5/6

The Tyvek® Labo chemical protection coverall is a suit with a hood and with a slip-resistant sole. The 3-piece hood and gusset provides an optimal fit. Elasticated hoods, sleeves and ankles as well as a glued-on elastic in the back area ensure a secure fit. This robust chemical coverall is lighter than other suits weighing less than 250 g per suit.

To order coverall Tyvek® Labo

Size	S	М	L	XL	XXL
Order No. (non-sterile - 25 pieces)	100220	100221	100222	100223	100224
Order No. (sterile - 6 pieces)	100215	100216	100217	100218	100219



# Protective coverall EasySafe®

Light type 5/6 coverall for particles and light spray

The type 5/6-protective coverall from PE spun fleece offers protection against fibres, particles and light spray mist is optimally designed for cleaning and other auxillary work in the laboratory, disposal of contaminated waste (e.g. asbestos) and inspection and overhaul work. The coverall is very comfortable to wear and is antistatically treated in accordance to EN 1149-5.

To order coverall EasySafe®

Size	М	L	XL	XXL
Chest girth (cm)	92-100	100-108	108-116	116-124
Body height (cm)	168-176	174-182	180-188	186-194
Order No. (non-sterile - 100 pcs	125700	125702	125704	125706
Order No. (sterile – 6 pcs)	100131	100132	100133	100134

## Expert knowledge - cleanroom clothing

# TEST METHODS: PARTICLE EMISSION OF STERILE PROTECTIVE CLOTHING IN CLEANROOMS

When working with toxic substances and CMR drugs protective clothing must be worn even under cleanroom conditions in accordance with the European PPE guidelines 89/686/EEC or EU regulation 2016/425.

However, the type of cleanroom clothing normally worn does not provide sufficient protection.

Their use is a legal grey zone for the operator.

Certified protective clothing is often regarded as unsuitable for clean areas, due to the assumption that they emit too many particles.

For this reason Berner International has a special testing chamber, where particle emissions of protective clothing can be measured under real life-like conditions. The test chamber, also called 'Body Box', is based on a test process of the American "Institute of Environmental Science & Technology".

In contrast to other particle measurements methods of clothing items (e.g. Helmke Drum testing) the emission of particles in this test scenario will be measured while the piece of clothing is being actually worn be a person.

In a mini-cleanroom, the size being similar to a telephone box, the test subject has to perform the certain movements defined by the IEST. For example, "straightening the arms", "walking with hand movements up to the shoulders and raised up knees" and squats. The exhaust air flow is tested with particle counters, so that the exact number of emitted particles per m³ air can be measured in various sizes. By repeating the experiment a fixed number of times the average number of emitted particles per type of protective clothing item (e.g. protective coverall Active Breath, sterile, Tyvek Classic+, sterile, etc.)

can be determined. If the procedure is adapted further to emulate the actual movements which are carried out in the laboratory, then the particle emissions will also be more realistic.

Using this body box we can specifiy the particle emissions of a person wearing protective clothing in a cleanroom and subsequently recommend suitable PPE. This guarantees optimal personal and also the necessary product protection in the cleanroom.



#### Criteria for cleanrooms

Numerous production steps for particularly sensitive products are now taking place in cleanrooms of various performance classes. Depending on the cleanroom class, a defined maximum particle concentration must not be exceeded. The maximum number of particles allowed is defined in ISO 14644-1 "air purity classes for cleanrooms and associated cleanroom areas" (see Table 1). Historically, the obsolete FED standard is often still given in overviews, although it was replaced over 10 years ago.

#### Cleanrooms for drug production

For drug production, on the other hand, classifications are applied according to the GMP Guidelines, Annex 1 (GMP = Good Manufacturing Practice), since the risk of contamination with microorganisms or pyrogens is also taken into account. The GMP guide includes guidelines for quality assurance in production processes and environments in the production of drugs, active ingredients, cosmetics, food and feed (see table 2).

#### Cleanroom clothing or protective clothing?

The limits listed in the tables are intended to protect the cleanroom or the product. When dealing with hazardous substances in the cleanroom (for example in the manufacture of cytostatics in the pharmacy) personal protection must not be neglected.

In accordance with the PPE regulation 2016/425 (formerly PPE directive 89/686/EEC), only suitable chemical protective clothing of the highest category III is permitted for the protection of employees with the handling of highly effective chemical hazardous substances. This protective clothing must be tested and certified. Their necessity must be checked by the operator in the context of the risk assessment and verified by means of appropriate certificates (Fig. 2).

Of course, the certified protective clothing must also meet the requirements for cleanroom and product protection. In the past, this was often a problem, as the disposable protective clothing released too many particles when used in the cleanroom.

New production methods for the disposable protective clothing now offer the possibility to manufacture certified protective clothing by means of an appropriate pre-treatment, wich are also suitable for clean-rooms.

Table 1: Air purity classes for cleanrooms and associated cleanroom areas.

Source: ISO 14644-1

ISO Classificatio	ո 0.1 կm	0.2 կm	0.3 կm	0.5 կm	0.1 կm	5.0 կm	SI	English former FED-STD-209E
ISO Class 1	10	2						
ISO Class 2	100	24	10	4	8			
ISO Class 3	1.000	237	102	35	83		M 1.5	1
ISO Class 4	10.000	2370	1.020	352	832	29	M 2.5	10
ISO Class 5	100.000	23700	10200	3520	8320	293	M 3.5	100
ISO Class 6	1.000000	237000	102000	35200	83200	2930	M 4.5	1000
ISO Class 7				352000	832000	29300	M 5.5	10000
ISO Class 8				3520000	8320000	293000	M 6.5	100000
ISO Class 9				35200000	83200000	2930000	M 6.5	100000

MEO

#### Test procedure: Particle emissions of protective clothing in cleanrooms

Particle emissions of clothing materials can be tested using various methods.



In the Helmke drum process (according to the guidelines of the Institute of Enviromental Science and Technology - IEST RP-CC003.4), the textile is put into a drum, which at first glance reminds of a washing machine. The drum rotates during the test with a predetermined number of revolutions, the air inside is sucked off and passed over a particle counter. Although the process is widespread, it unfortunately provides only a rough overview of the actual particle numbers of the textile. Thus the numbers are already changing, if the textile is only put together in a different way for the test.

#### 2. Suction method in accordance to ASTM F51 / F51M-00

On a test table, air is sucked through the test textile, the number of released particles is determined and calculated on the total clothing piece. The name "suction method" already shows the limits of the method, because only air permeable materials can be examined. When chemicals are used, frequently is provided with coatings, the method is therefore only limited or can not be used at all.

#### 3. Body-Box

Testing of protective clothing in a test chamber, also called body box, is also based on a test method of the American Institute of Environmental Science & Technology ". In contrast to the above-mentioned methods for particle measurement, this test-scenario takes into account the emission of particles while being worn. In a mini-clean room reminiscent of a telephone cell, the test person has to carry out defined movements according to the IEST data. The exhaust air flow is sampled with particle counters so that the exact number of particles dispensed per m³ of air in various sizes can be measured. By means of a defined number of repetitions per experiment, average particle emissions for each type of protective clothing (e.g. protective coverall Active Breath II, sterile, Tyvek Classic + sterile, .etc.) can be determined. If the method is further adapted to the real-life movements in the laboratory, particle emissions can also be specified in a more realistic manner. The test method in our body box allows to specify particle emissions through a person wearing protective clothing in the cleanroom and thus to make appropriate cleanroom recommendations. This ensures optimal personal protection as well as the necessary product protection in the cleanroom.



Fig. 2: Risk assessment

Type examination certificate for the product must be available

# Conclusion

Protective clothing for use in cleanrooms is available in different versions. When dealing with cytostatics, the use of chemical protective clothing is prescribed by law in Europe. This also applies to cleanroom operations. Certified protective clothing suited to cleanrooms, with today's manufacturing processes, offers safe protection against the hazardous substances and meets the requirements for use in the

Table 2: GMP-classes - EU classification. Source: EU GMPs Annex  $\mathbf{1}$  – Recommended limits for particle contamination

GMP- class	Maximum particles			
	At rest At rest		In operation	In operation
	0.5 կm	5 կm	0.5 կm	5 կm
Α	3.520	20	3.520	20
В	3.520	29	352.000	2.930
С	352.000	2.930	3.500.000	29.300
D	3.520.000	29.000	not defined	not defined

Table 3: Recommended threshold values for the microbiological contamination (a)

Class	Air- sample CFU/m3	Sedimentation plate (Diam. 90mm) CFU/4 hours (b)	Contact- plate (Diam. 55mm) CFU/plate	Glove impression 5 finger CFU/glove
А	< 1	< 1	< 1	< 1
В	10	5	5	5
С	100	50	25	
D	200	100	50	-



#### **Protective overboots PB3-3PB**

Type PB3 / PB3-B: The perfect addition for the Tychem® C overall

The protective overboots type PB3 / PB3-B with a slip-resistant and a liquid tight sole offers you maximum protection against aggressive chemicals. The protective overboots have also been tested as infection protection clothing in accordance to EN 14126. The universal shape and elasticated seam at the top as well as the tie strap guarantee a comfortable fit and make them quick and easy to put on and take off.

**To order** Protective overboots Type PB 3 / PB 3-B

Size	uni
Order No. (non-sterile - 15 pairs)	100044



#### **Protective overboots Active Breath**

Cleanroom compliant chemical protection with slip-resistant sole

For optimum protection Berner International offers protective overboots which are a useful addition to the new coverall. The protective overboots Active Breath are made from the same tested and certified protective material. Elasticated bands and additional ties ensure a good fit around the foot and a particle-tight connection to the overall. A slip-resistant sole makes walking easier and provides a safe grip.

To order Protective overboots Active Breath II

Size	uni
Order No. (non-sterile - 20 pairs)	100213
Order No. (sterile - 25 pairs)	100214



# Protective overboots Tyvek® Isoclean®

Cleanroom overboots suitable for ISO-class 4 with slip-resistant sole

The overboots Tyvek® Isoclean® made by DuPont combine all the protective properties of Tyvek material with the requirements of controlled areas in cleanrooms. The Tyvek material has been specially cleaned and sterilised and is therefore suitable for cleanrooms up to ISO class 5.

To order Protective overboots Tyvek® Isoclean®

Size	S	M	L	XL
Order No. (non-sterile - 50 pairs)	_	125564	125565	-
Order No. (sterile - 50 pairs)	100123	100124	100125	100126



#### **Protective overshoes**

Cleanroom protection for your feet type PB4 / PB4-B

The Berner protective overshoes with a certified slip-retardant sole and liquid-tight coating offers maximum protection. The universal fit and the elasticated ankle guarantee a comfortable fit and are easy to put on and take off.

- + Personal protective equipment (PPE) category III
- + Very high barrier function: comprehensive permeation tests with various cytostatics
- + Low in particles

#### **To order** Protective overboots

Size	uni
Order No. (non-sterile - 40 pairs)	125501
Order No. (sterile - 30 pairs)	125502



# Safety boots S5

Puncture-resistant boots for use during pandemics

These safety boots of the highest safety level S5 with a slip-resistant sole offer maximum protection for pandemics. Due to the high stability and optimal shape the work safety boots are very comfortable to wear. Additionally, the boots are certified as infective protection clothing to EN ISO 20345. The protective boots have reinforced toe caps and a steel layer and are anti-statically treated.

To order Safety boots S5 - shaft height 35 cm

Size	38	39	40	41	42
Order No. (1 pair)	125571	125572	125573	125574	125575
Size	43	44	45	46	
Order No. (1 pair)	125576	125577	125578	125579	



## Hood Tyvek® Isoclean®

Additional particle protection in cleanrooms

The hood Tyvek® Isoclean® manufactured by DuPont combines the protective properties of the well-known Tyvek® material with the requirements of controlled areas in cleanrooms. The hood was specially cleaned and sterilised and is suitable for cleanrooms up to ISO-class 5.

To order Hood DuPont Tyvek® Isoclean®

Size	uni
Order No. (sterile - 100 pieces)	125750



## **Protective gown**

The proven partial protection against chemicals, cytostatic and biological agents type PB4 / PB4-B  $\,$ 

Partial body protection with completely closed front, extra long cut and a raised collar.

- + Liquid impermeable coating front and sleeves
- + Sleeves have ultrasonically sealed seams for high penentration protection
- + Comprehensive permeation tests
- + Breathable back
- + Neck velcro fastening
- + With ties at the waist
- + Available with elasticated or knitted cuffs
- + Optimal for cleanrooms (gown worn over the cleanroom overall)

#### To order Protective gown with knitted cuffs

Size	S	М	L	XL
Order No. (non-sterile - 15 pcs)	6700	6800	6900	100072
Order No. (sterile - 10 pcs)	6701	6801	6901	100073

#### **To order** Protective gown with elasticated cuffs

Size	М	L
Order No. (non-sterile - 15 pcs)	6500	6550
Order No. (sterile - 10 pcs)	6600	6650



# **Apron Tyvek® Classic Plus**

Additional protection as required

Partial protection version suitable, for example, with reusable clothing systems made from the well-known Tyvek® Classic Plus material. The apron has a neck loop and a tie at the waist.

- + Partial protection for the front part of the body
- + With neck loop and waist tie
- + Comprehensive documentation
- + Certified-material apron not tested separately as PPE (type 4PB)

#### To order Apron DuPont Tyvek® Classic Plus

Size	uni
Order No. (non-sterile - 25 pcs)	6950
Order No. (sterile - 40 pcs)	100070



# Tychem® F protective gown

Protection against infection & many organic and highly concentrated inorganic chemicals - type PB3 / PB3-B

The DuPont Tychem® F protective gown provides a very high barrier against numerous organic and inorganic chemicals while offering protection against biological hazards (meets the requirements of EN 14126). The shin-length protective gown has long sleeves with elasticated wrists, hook and loop neck closure and and waist bands. The seams are overtaped with barrier tape for extra resistance. The product has antistatic treatment on the inside.

To order Tychem® F protective gown

Size	S/M	L/XXL
Order No. (non-sterile - 25 pcs)	100083	100084



# Tychem® F apron

Protection against infection & many organic and highly concentrated inorganic chemicals - type PB3 / PB3-B

The apron Tychem F protects the body and is shin length. The protection against biological agents (according to EN 14126) as well as concentrated organic and inorganic chemicals (please observe permeation table) is particularly good. The apron has an antistatic finish on the inside.

To order Tychem® F Apron

Size	S/M	L/XXL
Order No. (non-sterile - 25 pcs)	available o	n request



#### **Protective oversleeves**

Suitable protection for sleeves in cleanrooms against chmmicals, cytostatics and biological agents type PB4 / PB4-B.

The low particle oversleeves can be used wherever all over body protection is not required. Due to the liquid-impermeable coating safety protection of the arms is always guaranteed. The cone-shaped cut makes donning easy, universal shape and wearing comfort.

- + Comprehensive permeation tests
- + Ultrasonic sealed seams for high penetration protection
- + Available with knitted or elasticated cuffs

#### To order Protective oversleeves

	Knitted cuffs	Elasticated
Order No. (non-sterile - 50 pairs)	6000	6200
Order No. (sterile - 40 / 30 pairs)	6001	6300



## Protective oversleeves Tychem® C

Protective oversleeves type PB3 / PB3-B: Protection of the arms against chemicals and biological agents

The Tychem® C protective oversleeves offer protection against concentrated inorganic acids and biological agents in accordance with EN 14126.

- + Category III personal protective equipment (PPE)
- + Type-tested and certified
- + Chemical protective clothing type PB3 to EN 14605
- + Infectious protective clothing type PB3-B to EN 14126
- + Coating impermeable to liquids
- + Seams liquid-tight overtaped

#### **To order** Protective oversleeves Tychem® C

Size	uni
Order No. (non-sterile - 25 pairs)	6455



# Isolator protective oversleeves

Protection of the isolator oversleeves permeation type PB4

When working with CMR drugs (e.g. cytostatics) all exposed protective materials are subject to potential contamination by a particular substance. The protective oversleeves which are connected to the isolator also lie within the exposed area. However, to maintain a changing rhythm here is very difficult. For this reason Berner International offers a patented oversleeves system, which can be pulled over the existing isolator oversleeve system. The oversleeve system consists of tested and certified PPE and is to be replaced daily. In this way permeation in the fixed part of the isolator oversleeves can be avoided.

#### To order Isolator sleeve covers

Size	uni
Order No. (sterile - 15 pairs)	6451



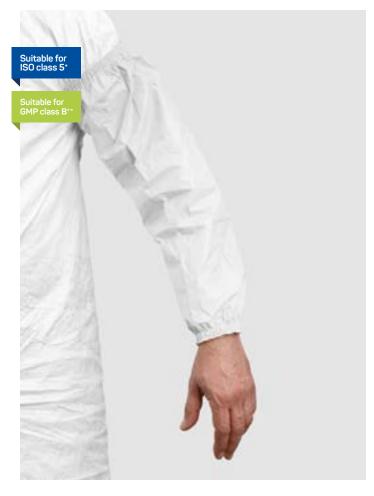
# Tychem® F protective oversleeves

The proven partial protection against chemicals, cytostatics and biological agents type PB3 / PB3-B

Like all Tychem F products, the protective oversleeves Tychem F offer particularly high protection against concentrated organic and inorganic chemicals and biological agents especially in the exposed arm area. Elasticated for a perfect fit.

To order Tychem® F protective sleeves

Size	uni
Order No. (non-sterile - 25 pieces)	available on request



# Tyvek® IsoClean oversleeves

Partial protection for use in cleanrooms

Particularly low-particle cleanroom protective clothing with a good barrier effect against cytostatics. The cleanroom oversleeves meet the requirements for controlled areas in cleanrooms up to ISO class 5. The Tyvek material is specially cleaned and gamma-sterilized. The oversleeves are packaged under controlled conditions and double-wrapped.

To order Tyvek Isoclean protective sleeves

Size	uni
Order No. (sterile - 100 pieces)	100122





### **CERTIFIED RESPIRATORY FACE MASKS**

Certified, particle-filtrating respiratory face masks in accordance to EN 149 of levels FFP-2 and FFP-3 for use in the laboratory. According to the application area masks can be used for protection against particles and aerosols when handling cytostatics, working with biological agents and viruses or other hazardous substances. All masks are type-tested and certified in accordance to EU directive 89/686/EEC or PPE EU regulation 2016/425

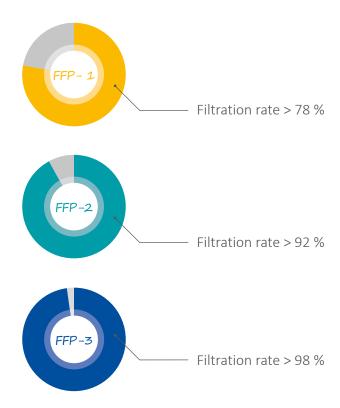
Attention - FFP-masks are unsuitable for gases!

For protection against gaseous substances use a reusable partial or full face mask with an appropriate filter.

#### **OVERVIEW OF FFP-FILTRATION RATES\***

Example: For a filtration rate of 92 %, 8 % of particles go through the mask (if worn correctly).

\* FFP Classification in accordance to EN 149



# No

# Expert knowledge respiratory masks FILTRATION OF NANO PARTICLES

Filtering half masks serve as respiratory protection against harmful dusts. However, the requirements for the retention capacity of so-called FFP masks described in the European standard EN 149 relate only to microparticles with an average size of 0.4-10  $\mu$ m. Even smaller and thus especially alveolar nano particles are not taken into account during the test procedure (see Fig. 1).

More and more nano particles are used in many manufacturing processes, such as the industrial production of cosmetics, in coating processes or in food production. This increases the risk of occupational exposure. Owing to their small size, unbound nano particles can easily enter the body. They can penetrate through the respiratory tract into the pulmonary vesicles, from there into other organs are transported and cause damage (see figure 2). Therefore, preventive protective measures are also required against this dust fraction.

Within the framework of a "Nano" research project, a special test method was developed in cooperation with the University of Milan to test the degree of protection of BLS masks against nanoparticles. Thereby the retaining capacity of the nanoparticles was tested from carbon to metal oxides.

It has been found that the special filter material of BLS masks is capable of retaining more than 97% of nanoparticles. BLS masks therefore offer a respiratory protection, which goes well beyond the requirements of EN 149.

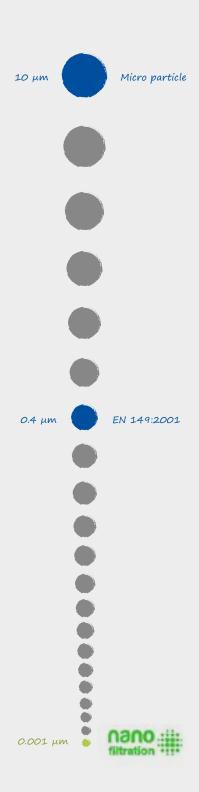


Fig. 1: Filtration of nano particles



#### **BLS 860**

Respiratory folding mask for nano particles up to 0.001 µm

The Berner FFP3 folding respiratory mask BLS 860 provides optimum protection against particles and aerosols. The special filter material fulfills the requirements of EN 149 and also safely retains nano particles up to 0.001  $\mu m$ . These particles usually penetrate the body very easily due to their small size.

To order BLS 860 repiratory folding mask

Size	uni
Order No. (non-sterile- 10 pieces)	100180



## **BLS Zero 31**

Respiratory mask for nano particles up to 0.001 µm

The FFP3 respirator mask BLS Zero 31 provides optimum protection against particles and aerosols as a moulded mask. A micro mesh on the surface protects the mask from dust accumulation and mechanical damage to the actual filter material.

The special filter material fulfills the requirements of EN 149 and also safely retains nanoparticles up to 0.001  $\mu m.$  These particles usually penetrate the body very easily due to their small size.

To order BLS Zero 31 respiratory mask

Size	uni
Order No. (non-steril e- 10 pieces)	100181



# Surgical mask

Face-mask with elasticated bands

The Foliodress surgical mask from Hartmann is made of hypoallergenics particularly soft and supple non-woven material. It is latex-free, with a special micro-germ filter and has soft elastic bands for fixing behind the ears. The mask meets the requirements of a type II according to EN 14683: 2014 and is latex-free.

To order Foliodress face mask loop

Size	uni
Order No. (non-sterile- 50 pieces)	H-9925372



## FFP-3 Respiratory mask

Protection against particles, aerosols and viruses

The pre-shaped FFP-3 respiratory mask with integrated valve and fixed mask body made by Uvex Safety. The new, optimised design of this FFP-3 moulded mask in connection with the soft sealing lip makes it very comfortable to wear while optimising the protective function. This respiratory face mask is suitable for handling with CMR drugs (e.g. cytostatics, virostatics, etc.), biological agents and viruses.

To order Uvex respiratory pre-shaped mask FFP-3 D

Size	uni
Order No. (1 piece)	121287



# FFP-3 Respiratory mask

Pre-shaped mask with high wearing comfort

The FFP-3 respiratory mask made by Moldex has an integrated valve and pre-shaped mask body. A sealing lip with elastic straps ensures maximum comfort. Donning and removing of the mask is easy due to the moulded shape and ensures a perfect fit. This face mask is suitable for handling CMR drugs (e.g. cytostatic subtances, virostatics, etc. ) biological agents as well as viruses.

To order Moldex respiratory pre-shaped mask FFP-3 D

Size	uni
Order No. (1 piece)	121262



# FFP-3 Respiratory folding mask

Folding mask for all face shapes

The FFP-3 respiratory folded face mask with integrated valve manufactured by Uvex Safety. Due to the special design this FFP-3 mask the correct fit (and thereby ensuring the protective function) can be easily checked. The elasticated straps at the sides ensure a tight and proper fit of the mask. Also available as a sterile version. The latex-free folding mask is also very spacesaving to store.

#### To order Uvex respiratory folding mask FFP-3 D

Size	uni
Order No. (non-sterile - 1 piece)	121285
Order No. (sterile - 4 pieces)	121286



## FFP-3 Respiratory folding mask

Respiratory folding mask without exhalation valve

Developed for working in cleanrooms, in areas where potential particle emissions in the form of respiratory air are to be avoided. The very high protective functions and a perfect fit are the distinguishing features of this mask. The CoolSAFE+ $^{TM}$  filter material offers optimum protection.

To order Dräger X-plore 1730 respiratory folding mask FFP-3 D

Size	uni
Order No. (1 piece)	121289
Order No. (sterile- 4 pcs)	121297



## FFP-2 Respiratory folding mask\*

Latex-free folding mask with reduced breathing resistance

FFP-2 folding mask made by Uvex for protection against dust, aerosols, and aerosol mist. The mask has passed the dolomite dust test for intense dust generation and is completely latex-free. Suitable for all applications, where FFP-2 filtration is sufficient (see risk analysis).

**To order** Uvex respiratory folding mask FFP-2 D

Size	uni
Order No. (1 piece)	121272



## Respiratory full face mask\*

For professional applications for the highest demands

The Dräger X-plore® 6530 full face respiratory mask has been designed for professional applications. In combination with the appropriate X-plore respiratory filter (Rd40 thread to EN 148-1) the mask provides the perfect protection for various applications, eg. in the chemical or pharmaceutical industry but is also suitable for use in infection protection sets and for use in pathology. Filters exist for virtually all fields of application: We recommend the combi-filter type: 1140 - A2B2E2K2 Hg CO NO-P3 R D. This filter is suitable for many different applications areas and thereby reducing the sources of error as well as storage costs for many filters.

**To order** Dräger X-plore® 6530 respiratory full face mask & Respiratory combi-filter for full face mask X-plore 6000-series

Mask: Order No. (1 piece)	121290
Kombi-filter: Order No. (1 piece)	121291

# Safety goggles Eye protection is of major importance in the laboratory. According to the application area and risk assessment different models of eyewear are suitable. From simple laboratory glasses to safety eyewear with frames to gas-tight or autoclavable safety goggles. Your safety is at stake. You would like to know more? Simply use your smartphone or tablet to access www.berner-safety.de/glasses



#### **SAFETY GLASSES**

Safety glasses are subject to, like the other parts of personal protective equipment (PPE) in Europe, the EU directive 89/686/EEC or PPE Regulation 2016/425. Only when the requirements of the directive and the particular relevant standards habe been fullfilled, a manufacturer is allowed to bring the PPE to the market.

As part of the risk analysis (the key element of health and safety at work) the employer has to assess the hazard potential of individual tasks / activities and provide suitable and tested protective equipment. The employee is then required to wear this equipment for these particular tasks.

The main standard for safety goggles is EN 166 (Personal eye protection- requirements). Depending on the particular field of application which are safety glasses additional EN standards may also be relevant (EN 167 – EN 175, EN 379 and several EN ISO standards on eye optics). Further details and ordering information on the standards can be obtained from your national standards organisation.

## **AUTOCLAVABLE SAFETY GLASSES**FOR GMP-COMPLIANT PRODUCTION

Specially for sterile applications autoclavable safety glasses are now available with an anti-fog coating.



## Safety glasses Super fit CR

First autoclavable safety glasses with "Antifog"-Effect

Professional work safety in laboratories, clinics, cleanrooms etc. For special demands Uvex has developed the first autoclavable safety goggles with antifog coating. The glasses are extremely light, flexible soft side arms fits all face shapes well, is very comfortable to wear with a wide field of vision and can be easily combined with further personal protective equipment (PPE). The glasses can be autoclaved repeatedly at a maximum of 121° C .

#### **Product highlights**

- + Large field of vision
- + Autoclavable at 121° C
- + Optimum fit
- + Anti-fog
- + Extremely light

#### To order Uvex Super fit CR

Size	uni
Order No. (1 piece)	121706



## Safety glasses Super f OTG CR

Safety glasses with side protection

The glasses fit perfectly, have a wide field of vision and lateral spray protection. The special XST-temples make these safety goggles comfortable to wear and can be optimally combined with further personal protective equipment (PPE). The safety goggles is also suitable for spectacle wearers. The Super f OTG CR glasses can be autoclaved several times at 121° C.

#### **Product highlights**

- + Very large field of vision
- + Autoclavable at 121°C
- + Optimum fit due to XST-arms
- + Anti-fog
- + Can be worn over spectacles

#### **To order** Uvex Super f OTG CR

Size	uni
Order No. (1 piece)	121711



## Cleanroom goggles Ultrasonic CR

Autoclavable full vision safety goggles

The full vision safety goggles Ultrasonic CR with indirect ventilation ensure comfortable and irritation-free conditions. Due to the wide field of vision everything at the workplace is always visible at a glance.

The shape of the safety glasses can be easily adjusted using the soft silicone headband and can be optimally adjusted to individual requirements and can be optimally combined with personal protective equipment (PPE). These glasses are also suitable for spectacle wearers.

#### **Product highlights**

- + At 121° C autoclavable
- + Anti-fog coating
- + Suitable for cleanrooms to ISO class 5 (to ISO 14644-1)
- + Or class B in accordance to GMPguidelines annexe 1
- + For spectacle wearers

#### To order Uvex Ultrasonic CR

Size	uni
Order No. (1 piece)	121716



## Safety goggles 9405

Full vision safety goggles with "anti-fog" in sterile and non-sterile

The completely enclosed full vision safety goggles made by Uvex Safety guarantee optimum protection against mechanical risks, liquids and coarse dust. The flexible soft shape and the adjustable strap offers exceptional comfort, even when worn over spectacles. Especially in combination with respiratory masks these goggles always guarantee a clear vision.

#### **Product highlights**

- + Anti fog coating
- + Indirect ventilation
- + Can be worn over glasses

#### To order Uvex 9405

Size	uni
Order No. (sterile - 1 pc.)	121405
Order No. (non-sterile- 1 pc.)	121406



## Gas-tight safety goggles Fahrenheit SA

For handling gases and airborne viruses

The 3M full vision safety goggles Fahrenheit SA is comfortable to wear and is suitable for wearing over spectacles and in combination with respiratory masks. The acetate lens gives a good field of vision, high chemical resistance and impact resistant up to 120m/s. Naturally the safety goggles are equipped with an "anti-fog"-coating and 100% UV-filtration. The "SA" version of these safety goggles is gas-tight. The application range of these safety glasses extend from working with chemical substances, which change into the gaseous phase at room temperature to working with dangerous biological agents. For example, these safety goggles correspond to the recommendations made by the German Robert-Koch-Institute (RKI) for anti-infection sets (type 1) for the protection of current epidemics such as Ebola.

To order 3M Fahrenheit SA

Size	uni
Order No. (1 piece)	121730



## **Gas-tight safety goggles Ultravision**

For handling gases and airborne viruses

These full vision safety goggles made by Uvex Safety are fundamentally different from other safety goggles. While standard safety goggles have indirect ventilation, the Ultravision model is gas-tight. These goggles are ideal for working with chemical substances, which turn into the gaseous state at room temperature, but they are also suitable for working with hazardous biological agents. These safety glasses meet the specifications of the German Robert-Koch-Institute (RKI) for infection protection sets (type 1) to safeguard against epidemics such as the Ebola outbreak.

#### **Product highlights**

- + Gas-tight
- + Anti-fog coating
- + Good protection and comfortable fit

#### To order Uvex Ultravision

Size	uni
Order No. (1 piece)	121726

Shock with low energy (45m/s)

Shock with high energy (190m/s)

Shock with medium energy (120m/s)



8

Arc

Molten metal

and hot solids

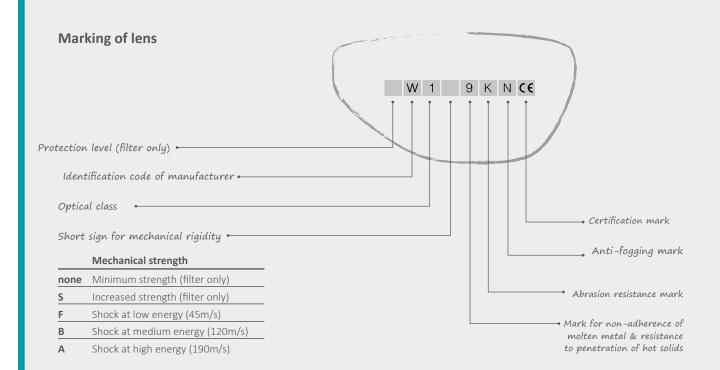
#### Marking on frame W 166 **C€** Identification code of . manufacturer EN standard number • Application range · Certification mark Designation Description of application range none General use Non-specific mechanical risks, hazards due to UV- and/or visual IR-radiation Symbol of resistance from high speed particles Liquids Liquids (drops and spray) 4 Dust, grain size >5ym Coarse dust Mechanical strength Gas and particulate Gases, vapours, mist, smoke and dust, **none** Minimum strength(only filter) matter grain size < 5ym Increased strength (only filter)

Electric arcs of short circuits

Metal sputtering and penetration of

in electrical appliances

hot solids







## PROTECTION FOR HEALTH CARE WORKERS IN EPIDEMICS AND PANDEMICS

In general, one talks of an outbreak of a disesase, if the number of people affected by a certain infectious disease in a specific region or over a specific time period exceeds the expected number of illnesses.

If the disease continues to spread across national borders and continents it is known as a pandemic, in the field of veterinary medicine it is called panzootics.

For the protection of health care workers, who enter these hazardous areas, Berner International offers complete pandemic sets of different configurations. Each of these sets comprise a complete set of personal protective equipment (PPE) for one person and are in line with the recommendations of the German Robert-Koch-Institute (RKI).

On request we are also able to put individual sets together to suit any special requirements.

#### **ANTI-INFECTION SETS**

Multi-resistant pathogens are currently on the rise in numerous establishments in the health care sector. New infectious diseases and changing ways of transmission present new challenges in terms of occupational safety for hospitals, care homes, emergency services, but also laboratories.

According to the relevant biological risk goup classification / biosafety levels, the infection sets by Berner International offer you safe protection in hazardous situations. Whether standard or individual sets suited to specific needs - we will be pleased to advise you.



## Pandemic Type 1 - Version A

Pandemic protection set

The BERNER pandemic protection set has been developed for health care workers, who remain within the infectious area for a limited periode of time (max. 8 hours). The set meets the recommendations of the German Robert-Koch-Institute (RKI) for infectious protection sets, version 1.

In line with the guidelines of the RKI, for this type of infection protection set, due to the absence of a gas filtered mask, only a limited decontamination is possible.

#### The set consists of:

- + 1 type 3 liquid-tight chemical protective coverall: **DuPont Tychem® C protective coverall**, category III, pressure-tight max. 2 bar, additional tested as protective clothing against infective agents to EN 14126 (type 3-B)
- + 1 pair of **protective overboots type 3-B**, tested as protective clothing against infective agents to EN 14126 (type 3-B)
- + 1 particle filtering **Uvex FFP3 respiratory mask** as per EN 149, retention capacity at least. 99%
- + 1 gas-tight Uvex safety goggles
- + 1 pair BERNER Nitrile chemical safety gloves Manu N with additional virus test to ASTM F1671.
- + 1 pair **BERNER Latex chemical safety gloves Manu L** extra thick material with additional virus test as per ASTM F1671.
- + 1 roll water proof duct tape for sealing the joins
- + 1 waste bag
- + 1 cable tie
- + 1 picture guide how to don PPE in D/GB
- + Comprehensive PPE documentation

#### To order Pandemic protection set- type 1 - Version A

Size	М	L	XXL
Order No. (1 set)	4178	4180	4182

## Pandemic Type 1 - Version B

Pandemic protection set

The BERNER pandemic protection set has been developed for health care workers, who remain within the infectious area for a limited periode of time (max. 8 hours). The set meets the recommendations of the German Robert-Koch-Institute (RKI) for infectious protection sets, version 1. This version contains a set of safety boots.

In line with the guidelines of the RKI, for this type of infection protection set, due to the absence of a gas filtered mask, only a limited decontamination is possible.

#### The set consists of:

- + 1 Type 3 liquid-tight chemical protective coverall DuPont Tyvek® 800J C protective coverall of the highest category III, additionally tested as protective clothing against infective agents to EN 14126 (type 3-B)
- + 1 Pair of **S5 work rubber safety boots** with a puncture-resistant sole (EN ISO 20345) and steel toe cap
- + 1 particle filtering **Uvex FFP3 respiratory mask** as per EN 149, retention capacity at least 99%
- + 1 gas-tight 3M safety goggles
- + 1 pair **BERNER Nitrile chemical safety gloves Manu N** with additional virus test to ASTM F1671.
- + 1 pair BERNER Latex chemical safety gloves Manu L- extra thick material with additional virus test as per ASTM F1671.
- + 1 roll water proof duct tape for sealing the joins
- + 1 waste bag
- + 1 cable tie
- + 1 picture guide how to don PPE in D/GB
- + Comprehensive PPE documentation

#### To order Pandemic protection set- type 1 - Version B

Size	M	L	XL	XXL	
Shoe size	40	42	44	46	
Order No. (1 set)	4185	4186	4187	4188	_

Further shoe sizes available on request!



## Pandemic Type 2

Pandemic protection set

The BERNER pandemic protection kit has been developed for emergency personnel who are continuously exposed to a hazardous area for an extended period of time. It meets the requirements of the Robert Koch Institute (RKI) of a type 2 infectious protection. The full mask with the appropriate filter allows for easier breathing, protects against biological pathogens and also absorbs the gases that are generated during decontamination. According to the provisions of the RKI, standardized decontamination is possible with this type of infection protection kit.

#### The set contains:

- + 1 type 3 liquid-tight chemical protective coverall:
  - DuPont Tychem® C coverall of the highest category III, additionally tested as protective clothing against infective agents to EN 14126 (type 3-B)
- + 1 pair of **S5 work safety boots** with a puncture-resistant sole (EN ISO 20345) and steel toe cap
- + 1 respiratory full face mask Dräger X-plore with suitable respiratory combination filter
- + 1 pair BERNER Nitrile chemical safety gloves Manu N with additional virus test to ASTM F1671.
- + 1 pair BERNER Latex chemical safety gloves Manu L- extra thick material with additional virus test as per ASTM F1671.
- + 1 roll water proof duct tape for sealing the joins
- + 1 waste bag
- + 1 cable tie
- + 1 picture guide how to don PPE in D/GB
- + Comprehensive PPE documentation

#### To order Pandemic protection set - type 2

Size	L	XXL
Shoe size	41	44
Order No. (1 set)	4195	4197

Further shoe sizes available on request!









## CONSUMABLES FOR THE LABORATORY

In a laboratory various tasks require the use of different tools. For example, prep mats offer good protection against the contamination of surfaces, withdrawal cannula make multiple extraction of liquids from vials much easier and spillkits contain the complete set of personal protective equipment for the elimination of spills.



EXPERT OPINION
Know-How Spikes
Dr. Jürgen Barth
Pharmacist StiL-Studienzentrale
Justus-Liebig-University, D-Gießen

#### Spikes without particle filter? - An opinion

"...There are further problems with **spikes containing filters** in the liquid channel. Cytostatics with particulate properties (liposomal formulations, nanoparticles or albumin-bound substances) and suspensions (azacitidine), but also mono-clonal antibodies should not be drawn up using these types of spikes. A suspension remains in the vial. A solution without any active ingredient is drawn up. The same applies to liposomal preparations or the liposomes are destroyed. Also, when drawing up, the (strong) shearing forces may cause the antibodies to be physically altered, damaged or depending on the filter material- absorbed."

The full text of this expert opinion is available on the web site of Berner International under the following address: www.berner-safety.de/spikes without filter



## Withdrawal cannula UltraSpike II

The UltraSpike II was developed for the drip-proof and complete emptying of vials. Due to the special side fixing clips the spike is positioned close to the plug of the vial. This means that the vial can be emptied leaving virtually no residual volume without retracting the withdrawal cannula (which would disable the ventilation).

Like all UltraSpikes the UltraSpike II also has a Halkey-Roberts valve. The special valve at the Luer-Lock adapter opens automatically and closes again when disconnecting the syringe. It is non-drip, easy to sterilise and offers increased contamination protection. To provide additional safety for the user, the chemo spikes contain a large 0.1  $\mu m$  PTFE Paclitaxel-resistant ventilation filter.

To order UltraSpike II – with plastic spike, without liquid filter

Order No. (50 pieces)

126217



## Withdrawal cannula Spike II

The Berner Spike II was developed for the drip-proof and complete emptying of vials. Due to the special side fixing clips the spike is positioned close to the plug of the vial. This means that the vial can be emptied leaving virtually no residual volume without retracting the withdrawal cannula (which would disable the ventilation).

To protect the user the ChemoSpike contains a large 0.1 μm PTFE Paclitaxel-resistant ventilation filter.

Model without liquid filter for drawing up viscous substances and monoclonal antibodies.

To order Spike II – with plastic spike, without liquid filter

Order No. (50 pieces)

126216



## Withdrawal cannula MicroSpike

The MicroSpike has been specially developed for the work with CMRdrugs such as cytostatics, virostatics and monoclonal antibodies etc. and offers maximum protection whilst being easy to handle.

Due to the extra long cannula vials with a narrow neck can also be drained completely and safely (handling similar to a cannula).

The MicroSpike has a particularly small residual "dead-volume" of only 0.17 ml.

To order MicroSpike – with extra long cannula, without liquid filter

Order No. (50 pieces)

126215

126211



## Withdrawal cannula UltraSpike

The UltraSpike are state of the art withdrawal cannula. The special valve at the Luer-Lock-adapter opens and closes automatically when connecting or disconnecting the syringe. It is non-drip, easy to disinfect and offers increased contamination protection.

To order UltraSpike – with plastic cannula and 5  $\mu$ m liquid filter

Order No. (50 pieces)

To order UltraSpike – with plastic cannula and 5  $\mu m$  liquid filter

Order No. (50 pieces) 126212

**To order** UltraSpike SKoF — with metal cannula but without liquid filter

Order No. (50 pieces) 126213



## Extra-Spike® Air SK Chemo\*

Multiple withdrawal cannula suitable for chemotherapy with a stainless steel cannula, integrated ventilation and hydrophobic, fibre-free 0.2  $\mu m$  filter

Compact form with large external ventilation filter.

To order Extra-Spike® Air SK Chemo, without liquid filter

Order No. (50 pieces) 112902872



## Swabs with high absorbency

The swabs Pagasling are made up of gauze EN 14079, 20-ply, and are from only one piece of medical gauze. The cut edges of the swab are positioned safely on the inside of the swab. The highly absorbent sterile swabs come in packs of four.

To order Sterile swabs Pagasling

Size uni, 4x20 pieces, sterile
Order No. H-4812742



## **SpillKit XP**

Emergency and cleaning set for cytostatics

The **BERNER SpillKit XP** provides all necessary tools for eliminating cytostatic contaminations easily and safely. The SpillKit XP has a type test certificate issued by an external notified body and is recommended by the DGOP and the ESOP.

- + Recommended by the DGOP and ESOP
- + Contains personal protective equipment (PPE) of the highest category III
- + Optimised for all types of cytostatic spills
- + Contains a tested coverall and overboots (please note the size)
- + Also available latex-free





#### To order SpillKit XP

Order No. for size M	4104
Order No. for size L	4112
Order No. for size XXL	4115

#### **To order** SpillKit XP – Latex-free version

Order No. for size M	4124
Order No. for size L	4133
Order No. for size XXL	4135



## **SpillKit XP Duo**

Emergency set for 2 people

The removal of spills should, if possible, be carried out by two people. The **BERNER Spillkit XP Duo** contains a complete set of protective equipment for two people as well as all necessary tools for the removal of spilt cytostatics.





#### To order SpillKit XP Duo

Order No. for size M/M	100101
Order No. for size M/L	100102
Order No. for size M/XXL	100103
Order No. for size L/L	100104
Order No. for size L/XXL	100105
Order No. for size XXL/XXL	100106



## **SpillKit**

Standard emergency and cleaning set for cytostatics

Our tried and tested **BERNER SpillKit** which contains a set of cytostatic protective equipment and other essential items – so that you are always well-equipped to deal with any spills relating to CMR drugs (e.g. cytostatic

- + Tested and certified PPE of the highest category III
- + Version with protective gown
- $\,+\,$  Contains all necessary tools e.g. Chemosorb-pad, cleaning cloths,  $\dots$
- + Comprehensive documentation

#### To order SpillKit

Size	uni
Order No.	4004



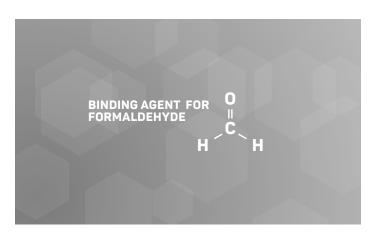
## SpillKit Formaldehyde

Emergency and cleaning set for Formaldehyde

The emgergency set Formaldehyde offers the complete personal protective equipment and the necessary accessories, to clean up Formaldehyde spills quickly and easily.

#### To order SpillKit Formaldehyde

Order No. for size M	100079
Order No. for size L	100080
Order No. for size XXI	100081



## Binding agent "Formaldehyde"

For the absorption of large quantities of Formaldehyde in hospitals, pharmacies and laboratories

Fast effective tool for soaking up Formaldehyde spills. This agent binds Formaldehyde easily and quickly and facilitates disposal. Including waste

To order Binding agent for Formaldehyde

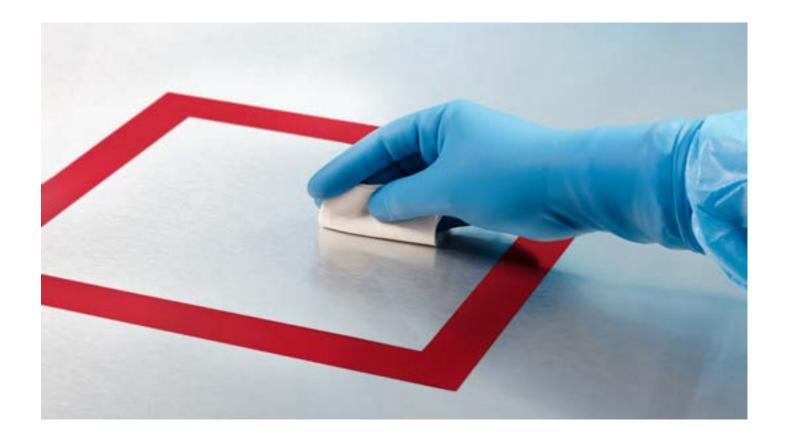
Order No. (1 piece)

100113



Poster SpillKit-instructions - suitable for cleanrooms www.berner-safety.de/spillkit\_poster





## Cytotoxic wipe sampling set

Easy and quick

When handling CMR drugs (e.g. cytostatics), unintentional cross-contamination from contaminated gloves, vials, protective clothing, shoes or wheels from transport trolleys, etc. can easily occur. Accidents or disturbances in airflow of safety cabinets can also lead to the release of cytostatic drugs. In the German MEWIP study (Monitoring-Effect Study for Wipe Sampling in Pharmacies) cytostatic drugs were found in 61% of all samples.

In cooperation with the Institute of Energy and Environmental Technology (IUTA e. V. ) in Germany, Berner International has developed a wipe sample set, with which contaminations from CMR drugs can be detected quickly and safely. Through regular monitoring weaknesses in the production, handling and cleaning processes are easily detected and corrected.

- + Validation of cleaning processes
- + Detecting sources of contamination
- + Control and optimisation of work processes
- + Proof of the optimum work procedure for your customers
- + Cost-effective analysis tool
- + Suitable for use by own staff
- + Analysis of numerous single substances or substance groups using economic multi-methods
- + Fast and detailed report
- + Can be performed at any time
- + Improved protection for your employees

#### To order Cytostatic wipe sampling set

Order No. Type 1	4155
Order No. Type 2	4156

#### Detectable Substances

5-Fluorouracil 6-Mercaptopurine Acemetacine Azathioprine Busulfane Capecitabine Carboplatin Carmustine Chlorambucil Cisplatin Clomiphene Cyclophosphamide Cytarabine Doxorubicin Docetaxel Etoposide Flutamide Gemcitabine Total-platinum Ifosfamide Methotrexate Mitomycine Oxaliplatin **Paclitaxel** Sulfamethoxazol

Tamoxifen

Thalidomide

The cost-effective multimethod (as in MEWIP) for the simultaneous analysis of various substances.

#### Multi-method 1

5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabine, Etoposide, Methotrexate, Paclitaxel, Docetaxel.

#### Multi-method 2

5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabin, Etoposide, Methotrexate, Paclitaxel, Docetaxel, total-platinum.

#### Multi-method 3

5-Fluorouracil, Cyclophosphamide, Ifosfamide, Gemcitabine, Etoposide, Methotrexate, Paclitaxel, Docetaxel as well as Cisplatin, Carboplatin, Oxaliplatin and total-platinum.

#### Platinum analysis

Cisplatin, Carboplatin, Oxaliplatin and total platinum.

Further substances available on request!





Extremely absorbent prep mats with with an impermeable lower layer for use in the laboratory. Minimizes time spent on cleaning.

- + Safe absorption of liquids
- + Available sterile and non-sterile

#### To order Prep mats

Order No. (56x41 cm - non-sterile- 50 pieces)	8100
Order No. (56x41 cm - sterile- 40 pieces)	8101
Order No. (42x26 cm - non-sterile - 50 pieces)	8000
Order No. (42x26 cm - sterile- 50 pieces)	8001
Order No. (61x44 cm - non-sterile - 50 pieces)	8700
Order No. (61x44 cm - sterile - 50 pieces)	8800



## ChemoSorb-Pad

For the absorption of large amount of liquids in hospitals, pharmacies and laboratories

The ChemoSorb-pad reliably absorbs and binds many chemicals. The liquids (e.g. cytostatic agents) are turned into a gel-like mass and thereby guarantees safe and effective elimination.

- + Binds liquids without drips
- + Liquid absorption up to 3 l
- + Suitable for CMR-drugs (e.g. cytostatics)
- + High absorption and easy handling
- + Ideal for emergencies (spill emergencies)
- + Also for absorbing bodily fluids

#### To order ChemoSorb-Pads- latex-free

Order No. (box with 10 pieces)	120016
Order No. (box with 50 pieces)	120014



## Cleanroom cloths ISYSOFT, ISYSOFT II and Cleanroom 100

Highest cleaning efficiency and optimal surface cleaning

ISYSOFT, Isysoft II (latex-free) and Cleanroom 100 cleaning wipes are optimised for cleaning in the cytotoxic field and for working with biological agents. Due to its special structure the material is extremely tear-resistant and absorbent.

#### To order Cleaning cloths

Order No. (Cleanroom 100 - non-sterile - 150 wipes)	121740
Order No. (Cleanroom 100 - sterile - 6 x 25 wipes)	121741
Order No. (ISYSOFT - non-sterile - 4 soft bags each incl. 25 pieces)	121500
Order No. (ISYSOFT - sterile - 50 x 2 wipes in special sterile packaging)	121501
Order No. (ISYSOFT-II - non-sterile - 4 soft bags each incl. 25 pieces)	121507
Order No. (ISYSOFT-II - sterile - 50 x 2 wipes in special sterile packaging)	121508



## Cleaning tool I

Easy and fast cleaning of safety cabinets for difficult to access areas

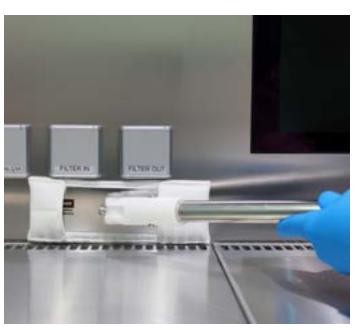
The regular cleaning and desinfection of safety cabinets is one of the standard tasks in a laboratory. However, in order to reach these hard to reach areas (e.g. rear wall, side windows), a person would have to lean the upper body into the potentially contaminated workspace. The BERNER cleaning tool for safety cabinets is ideally designed for this purpose. The device is easy to use and works well with standard cleaning wipes. These are easily fixed with the supplied clips on the cleaning tool.

Dimensions: ca. 170 x 90 mm; Length handle: 430 mm; Total length: 460 mm

Suitable cleaning wipes: ISYSOFT (Order No. non-sterile - 121500 or sterile -121501); also ISYSOFT II (Order No. non-sterile - 121507 or sterile- 121508)

To order Cleaning tool I

Order No. 802645



## Cleaning tool II

Autoclavable cleaning tool for safety cabinets and isolators

The cleaning tool II is made from stainless steel with a plastic joint. The device can be easily taken apart for cleaning and is autoclavable at 121 C.

Dimensions: 190 x 50 mm; Length handle: 580 mm; Total length: 650 mm

To order Cleaning tool II

Order No. 200662



## Mop covers for the cleaning tool II

Efficient and effortless cleaning of safety cabinets and isolators

The disposable mop covers were specially developed for the cleaning tool II. They are made up of a multi-layer microfibre polyester and are available in packs of two, as sterile wrapped. Also available pre-saturated with Isopropanol.

To order Mop covers cleaning tool II

Order No. Standard (double wrapped, PU= 2 pieces)	121742
Order No. IPA (pre-saturated with Isopropanol,	100100
double wrapped, sterile packaging, PU = 2 pieces)	100100



## **Tubular foil for the SealSafe®**

Liquid and aerosol-tight sealing of waste

Tubular foil for the waste disposal unit BERNER SealSafe®, BERNER SealSafe Sensor+® and the older version BERNER PactoSafe®. Developed for the easy disposal of waste when dealing with waste of CMR drugs and biological agents. Comprehensive permeation tests prove the cytostatic barrier function. Sealed waste can remain in the waste disposal container up to a week. The yellow coloured version of the tubular film is recommended for handling biological agents.

Order No. (sterile, colourless, for cytotoxics, 3x tubular foil)	1001
Order No. (non-sterile, colourless, for cytotoxics, 5x tubular foil)	
Order No. (non-sterile, yellow, for microbiological applications, 5x tubular foil)	1002



## Tubular film for the PolyStar®\*

Tubular film for the drug sealing device PolyStar®

The colourless, highly transparent polyethylene film (special mixture) is extremely tear resistant and waterproof. Roll with a plastic core.

Order No. (ca. 200 x 0.05 mm, 200 m)	048003
Order No. (ca. 220 x 0.05 mm, 200 m)	048005
Order No. (ca. 320 x 0.05 mm, 200 m)	048015
Order No. (ca. 200 x 0.10 mm, 100 m)	048004
Order No. (ca. 280 x 0.10 mm, 100 m)	048014
Order No. (ca. 320 x 0.10 mm, 100 m)	048016
Order No. (ca. 400 x 0.10 mm, 100 m)	048018
Order No. (ca. 200 x 0.20 mm, 100 m)	048007



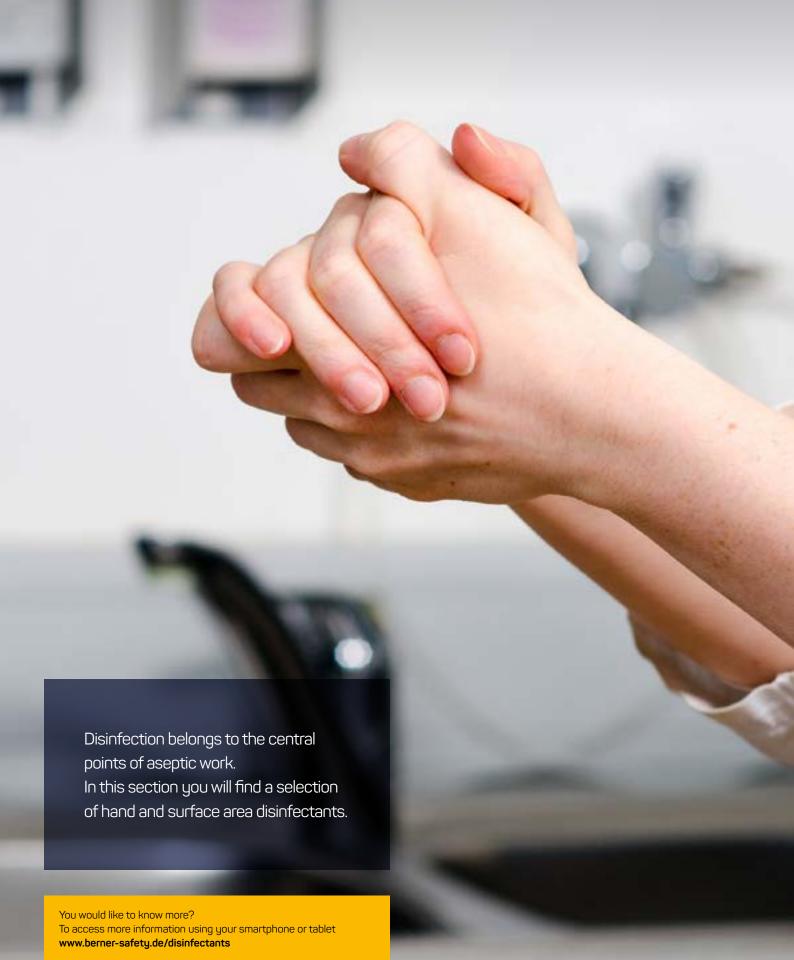
## **UV** light protection bag

For the safe storage and transport of light sensitive substances - with UV protection

The opaque brown coloured UV light protection bags protects for example, cytostatics reliably against UV radiation and guarantees storage and transport. The resealable zip lock bags facilitate the handling. The material thickness is 50 µm.

Order No. (ca. 150x200x0.05 mm, 300 pieces)	120150
Order No. (ca. 150x200x0.05 mm, 1.000 pieces)	12150200
Order No. (ca. 230x300x0.05 mm, 300 pieces)	120230
Order No. (ca. 230x300x0.05mm, 1.000 pieces)	12230300

# Disinfectants





## SURFACE AREA DISINFECTANTS FOR THE LABORATORY

Surface disinfectant in ready-to-use solutions, concentrates and user-friendly disinfecting wipes for simple and comprehensive disinfection of various surfaces.

Surface disinfecting agents should always be used with caution. Always read the label and product information before use.

### **TOWEL DISPENSER SYSTEMS**

Dispenser systems consist of practical wipe dispensers with specially selected tissues to meet high hygienic standards - optimised for use with surface disinfectants.

## HAND DISINFECTANTS AND HAND CARE

For efficient hand hygiene there is a need for hand disinfectants, consistent protection and care of hands, careful hand cleansing and the wearing of the right protective gloves. In the hand disinfectant categories, Berner offers complete solutions for your hand hygiene system.



## **Bode X-Wipes safety pack**

Disposable tissue dispenser for the easy and safe application in surface disinfection in hygienic areas

The tissue spender system Bode X-Wipes Safety Pack is suitable for the desinfection and cleaning of surfaces in all areas of clinics, care homes, laboratories and in areas where the highest level of hygiene and economy is required. Safety Packs are suitable for all liquid Bode surface disinfectants. The system is filled with a 2.5l solution of the disinfectant.

To order Bode X-Wipes Safety Pack

Size	Bode X-Wipes Safety Pack 90 tissues
Order No.	100173



## **Bode X-Wipes**

Universal applicable tissue dispenser system

The Bode X-Wipes dispensing system offers users universal applications and many advantages. The dispenser box is filled with a tissue roll (90 wipes) and a disinfectant. After a short exposure time, the wet tissues are available. The dispenser box can be easily cleaned and refilled.

To order Bode X-Wipes tissue dispenser

Size	Tissue dispenser (blue), for all tissue types	Bode X-Wipes tissue roll 6x90 tissues
Order No	H-9813700	H-9805562



## Bacillol® tissues

Ready-to-use alcoholic disinfectant wipes in handy dispenser box

For fast and convenient disnfection of alcohol-resistant surfaces and medical products. For areas, where comprehensive efficiacy is required within a short period of time. Listing: VAH, RKI (Area A), CE-marking in accordance with the Medical Device Directive (MDD), IHO-virucidal list, IHO-desinfectant list.

#### To order Bacillol® Tissues

Size Dispenser, 100 tissues		Re-fill pack, 100 tissues
Order No. (12 pcs)	H-9807201	H-9805041



## Bacillol® AF tissues

Alcoholic quick disinfecting wipes with comprehensive effectiveness in handy flowpack

Bacillol AF Tissues are pre-soaked, ready-to-use disinfectant wipes for fast and comprehensive disinfection of various alcohol-resistant surfaces. Bacillol AF Tissues dries quickly and leaves no residue on the surfaces. The high-quality, tear-resistant non-woven fabric can be safely and easily removed from the reclosable flowpack packaging thanks to the practical folding

#### To order Bacillol® AF Tissues

Size	6x Flowpack, 80 tissues per pac	k

Order No. H-9813113 (6 pieces)



#### Mikrobac® tissues

Alcohol-free disinfectant wipes for the disinfection of alcohol-sensitive surfaces and sensitive medical products

Mikrobac Tissues are suitable for uncomplicated cleaning disinfection of sensitive surfaces and of sensitive medical devices. The disinfecting cloths have very good material compatibility and are therefore also suitable for alcohol-sensitive materials.

#### To order Mikrobac® Tissues

Size	6x Flowpack, 80 tissues per pack
Order No. (6 pcs.)	H-9813870



### Kohrsolin® extra tissues

Disinfecting wipes containing aldehyde with virucidal action

Kohrsolin extra Tissues are suitable for uncomplicated, disinfecting cleaning of washable surfaces. Also suitable for targeted disinfection, if an extended spectrum is required.

Listing: VAH, CE-marking according to the Medical Devices Directives (MDD), IHO-virucide list.

#### To order Kohrsolin® extra Tissues

Size	6x Flowpack, 80 wipes per pack
Order No. (6 pcs)	H-9812022



## Bacillol® AF

Alcoholic fast acting disinfectant solution

The ready-to-use disinfectant solution Bacillol AF is a fast acting disinfectant with a comprehensive efficacy for alcohol resistant surfaces and medical products. Bacillol AF can be used wherever a fast acting and drying time as well as residue-free drying is required. Listing: VAH, RKI (field of action A), CE-marking according to the Medical Device Directive (MDD), IHO-Virucide list, IHO-disinfecting agent list

#### To order Bacillol® AF Surface disinfectant solution

Size	Box 20 pcs, 500 ml bottle	Box 10 pcs, 1000 ml bottle	Canister 5 l
Order No.	H-9802143	H-9802123	H-9802174



## Bacillol® plus

Alcoholic fast acting disinfectant solution

The ready-to-use disinfectant solution Bacillol plus is a rapid disinfectant for alcohol resistant surfaces and medical equipment.

Listing: VAH, CE-marking according to the Medical Devices Directive (MDD), IHO-virucide list.

#### To order Bacillol® plus surface disinfectant solution

Size	Canister 5 l
Order No.	H-9802091



## Sterillium® classic pure

The classical sterillium - dye- and perfume-free version

Sterillium classic pure is suitable for hygienic and surgical hand disinfection. Particularly suitable for users with sensitive skin, because Sterillium classic pure are free from dyes and perfumes. The high impact and long-term effects of up to six hours provides reliable protection against bacteria, yeast fungi and enveloped viruses.

Listing: VAH, IHO virucidal list, RKI list area A and limited virucidal

#### To order Disinfectant Sterillium® classic pure

Content of box	100 ml	500 ml	1000 ml	5 l
Order No.	H-9804660	H-9804670	H-9804680	H-9804690



## Sterillium® tissues

Practical disinfection wipes

Sterillium tissue protects reliably against infections such as bacteria, yeast fungi and enveloped viruses. Thanks to its practical shape, the Sterillium tissue provides safety in the workplace, on the road and in other hygienic situations.

List: VAH

#### To order Disinfectant Sterillium® Tissues

Size	Folding box, 10 pcs, individually sealed
Order No.	H-9812290



## Baktolan® protect

Water-in-oil cream for hand care

Baktolan protect for protection against long-lasting water-soluble pollutants and improvement of the natural protective function of the skin. The special rich formula with urea and beeswax cares for dry skin. In addition, Baktolan is free of silicone and preservatives and parabenes.

#### To order Hand cream Baktolan® protect

Size	Tube 100ml, 25 pcs
Order No.	H-9801400



## Baktolan® protect+ pure

Innovative water-in-oil lotion

Baktolan protect + pure offers long-lasting protection against water-soluble pollutants due its innovative formulation. At the same time, the perfume-free lotion supports the regeneration of skin treated with bisabolol and strengthens the natural protective function of healthy skin. Baktolan protect + pure absorbs quickly and does not leave a greasy film.

To order Hand care Baktolan® protect+ pure

Size	Bottle 350 ml, 20 pcs
Order No.	H-9811822



## Baktolan® balm pure

Intensive nourishing, perfume-free water-in-oil balm

Baktolan balm pure stabilizes the acid protection coat of the skin, since the balm has been adjusted to the pH value of the skin (5.5). The ingredients vitamin E, allantoin and pantheol provide for an intensive care of the skin, smoothing, support the cell regeneration and soothe skin irritation and redness. Repeated daily use with Baktolan balm pure can reduce the risk of skin irritation.

To order Hand care Baktolan® balm pure

Size	Bottle 350 ml, 20 pcs	
Order No.	H-9803601	



## Baktolin® sensitive

Mild, nourishing cleansing lotion

Baktolin sensitive provides a gentle cleansing of the skin and hands and is at the same time mild and caring. Thanks to the moisturizing Allantoin and the skin-smoothing wheat protein, the skin is kept smooth and supple even in case of intensive and daily repeated use. The pH of 5.5 protects the skin's sensitive protective barrier.

To order Hand wash lotion Baktolan® sensitive

Size	Box, 20 pcs, 500 ml bottle	Box, 20 pcs, 1000 ml bottle
Order No.	H-9813331	H-9813341



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