

THE WORLD OF DISPOSABLE GLOVES

COMPACT GUIDE



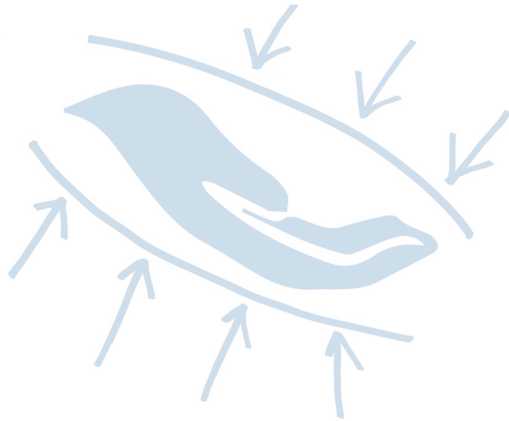
GENERAL

What are disposable gloves and why are they used?



A disposable glove is commonly made from natural or synthetic rubber that covers the whole hand and is used to protect the wearer against harmful environmental influences and/or used by caregivers in health care to protect themselves and patients from infections.

As the name implies, disposable gloves are designed for single use only and should be disposed immediately after use.



What does double donning mean?



Double donning, or the practice of wearing two layers of gloves, should provide maximum safety in situations with increased danger of glove failure, e.g. when dealing with particularly aggressive chemicals or high-risk patients.

Are powder-free gloves completely free of particles?



Due to different manufacturing processes, a minimum amount of powder residues may still be found within powder-free gloves. If the residual powder content is less than 2.0mg per glove (according to the test method described in the EN 455-3), the glove is by definition considered powder free.



Which types of disposable gloves exist?

Disposable gloves may vary in terms of material, size & shape, inner treatment, texture, color and sterility.

Material

Most commonly used raw materials for the production of disposable gloves are natural rubber latex (NR gloves), nitrile butadiene latex (NBR gloves) and PVC/softener paste (vinyl gloves).

Sizes and shape

Disposable examination and protective gloves are usually available in various sizes between XS and XL and can be equally worn on the left or on the right hand (ambidextrous shape), whereas surgical gloves are offered in a higher variety of sizes and are anatomically shaped.

Texture

Gloves are offered in several different textures, from smooth to fingertip- or fully-textured varieties depending on the application.

Inner treatment

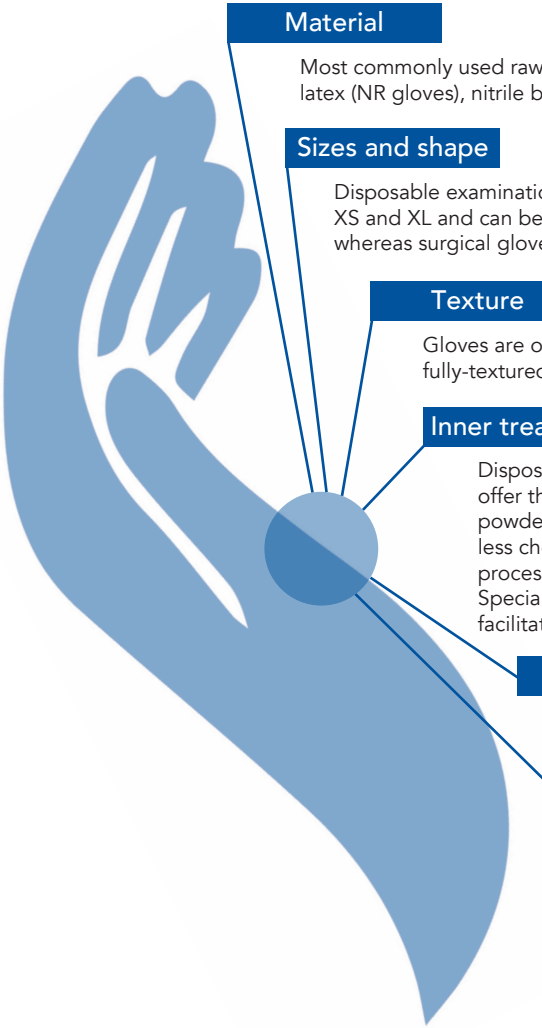
Disposable gloves can be either powdered or powder-free. Powdered gloves offer the advantage of easier donning even with sweaty hands. In general, powder free natural rubber gloves are more skin tolerable as they contain less chemical residues and water soluble protein thanks to the manufacturing process. Potential irritations are also minimized due to the absence of powder. Special manufacturing processes such as synthetic inner coating or chlorination facilitate easier donning, also for powder-free gloves.

Color

Disposable gloves come in various colors adjusted to the intended use or simple color preferences.

Sterility

Non-sterile gloves are mainly used for hygienic purposes or for self-protection, whereas sterile gloves are used for sterile procedures in hospitals or laboratories, where a contamination of patients and/or handled materials must be avoided.



MATERIALS

Which are the advantages and disadvantages of the different glove materials?



Natural rubber latex gloves or commonly just referred to as latex gloves offer good resistance against many acids and alkalis*. However, they are permeable to many solvents. Due to excellent elongation, latex gloves are very comfortable to wear and traditionally offer the best fit and feel. The main disadvantage is that natural latex proteins can cause or trigger latex allergies.



Nitrile gloves are made of nitrile butadiene rubber (NBR), which is a synthetic material, and can be used as an alternative for people allergic to natural latex or those who want to prevent an allergy. Another advantage is the enhanced resistance to many chemicals*, particularly to oils.






































Vinyl gloves are an economical alternative for applications where mechanical stress and barrier protection are of less importance. The skin-friendly material is suitable for users suffering from a latex or chemical allergy. One drawback is that the use of plasticizers as main component in the production of vinyl gloves disqualify them from handling fats and fatty foodstuffs.





* **CAUTION:** Before gloves are used in contact with chemicals please consult the chemical resistance list of the manufacturer. For all Sempermed gloves, this can be found at www.sempermed.com. Failure to observe this information can result in personal injury and/or material damage. In case of doubt obtain expert advice before use.

Which glove material should I choose?



Individuals sometimes perceive the material properties of latex, vinyl and nitrile differently. The following comparison provides a rough overview of the main material characteristics and may help the user to choose the right material for each application.

	Latex	Nitrile	Vinyl
Comfort	 		
Elasticity	 		
Grip / Tactility	 	 	
Tear resistance	 	 	
Elongation	800%*	600%*	300%*
Puncture resistance		 	
Chemical resistance		 	
Latex proteins	present 	Not present 	Not present 
Accelerators	present 	typically present  **	Not present 
Plasticizers	Not present 	Not present 	present 

-   Highly recommended
-  Recommended
-  Not recommended

* typical material elongation
 ** accelerator-free nitrile gloves are available on the market

ALLERGIES

What is the allergy potential of disposable gloves?



Water soluble proteins which can be extracted from natural latex gloves due to sweat can cause allergies and belong to the main reasons for allergic reactions towards disposable gloves. The allergy to natural latex proteins is an immediate type (Type I) allergy. In addition, allergic reactions to chemicals used in the production process are called type IV (delayed) allergies.



Is there a limit to the protein content of latex gloves?



How can one prevent a latex allergy from arising?



A latex allergy can be prevented by using gloves free of natural latex, such as nitrile or PVC gloves or by using powder-free latex gloves featuring a low protein level. In addition, consistent skin care including the good drying of hands after washing and the regular use of lotion can prevent an allergy.



Powder-free gloves undergo an intensive leaching and washing process in order to ensure that the leachable protein level is as low as possible. However, when using natural rubber latex (NR) gloves it is not possible to eliminate the exposure to allergenic proteins completely and there is no defined safe limit. Consequently, as part of risk control measures for any glove made from NR it must be clearly indicated on the primary packaging that the glove contains natural rubber latex plus an additional warning that the product may lead to allergic reactions needs to be included. Any labeling claims suggesting a protein level lower than the process limit of the producer are not allowed. The lowest allowable protein level that a manufacturer is allowed to claim for single use medical gloves is 50 µg/g in line with the standard EN 455-3.

QUALITY INDICATORS

Which are the most important quality indicators for disposable gloves?



Freedom from holes – AQL level

AQL is a statistical measure of quality assurance which determines how many defective units are allowed in a batch of manufactured products as assessed by testing a certain randomly drawn quantity. The lower the AQL level the higher the assumed level of quality and personal protection. For protective gloves applying to complex risks (EN ISO 374-1:2016) and medical gloves (EN 455), the standard maximum AQL of 1.5 for holes is required in Europe. This has to be determined according to more stringent inspection requirements as compared to an AQL level of 2.5 or 4.0, which are more likely to be used for applications for which barrier protection is less crucial.



Tensile properties – Force at Break

Even under extreme conditions disposable examination gloves have to offer maximum safety. Therefore robustness and tensile strength are of crucial importance. The tensile strength is defined as the force which has to be applied during an elongation of a test sample in relation to the original cross section of the specimen, until the test sample rips. The result is expressed in force (Newton) over area (square millimeters): N/mm², or the equivalent Megapascal (MPa). Tensile strength is a performance parameter of the material (independent of the crosssectional area) which is used in ASTM standards. European standards indicate force at break in Newton, which is a performance parameter of the device (glove) dependent on the cross-sectional area (wall thickness). In general, the lower the tensile strength, the easier gloves with the same wall thickness will tear if they are subject to a tensile force. The European standard for medical gloves (EN 455) prescribes a force at break (median) of ≥ 6 Newton for examination gloves made from natural or synthetic rubber, ≥ 3.6 Newton for gloves made from thermoplastic materials (eg. PVC) and ≥ 9 Newton for surgical gloves



It's the formulation and not the weight that counts!

The perceived high quality of a glove is often associated with higher weight, which is not necessarily true. Due to cost reduction most manufacturers use fillers which tend to be heavier than the polymers used in the glove. The moderate use of fillers is tolerable and can improve certain glove properties, whereas the excessive use of fillers can lead to a significant deterioration of glove performance characteristics. In addition, further factors affecting glove quality include the quality of raw materials used, specific formulations, manufacturing process and quality inspection system.



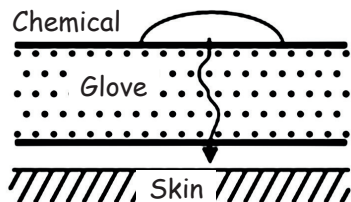
CHEMICAL HANDLING



What do permeation, penetration and degradation mean?

All three terms describe factors that affect the protection afforded against chemicals:

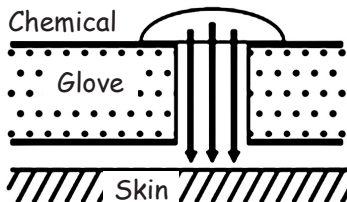
PERMEATION



Permeation describes the process in which a chemical diffuses and moves through intact glove material. It is usually indicated by the breakthrough time which is the time it takes a chemical to move completely through the material.

Tested according to EN 16523-1:2015.

PENETRATION



Penetration refers to the process in which a chemical moves through pinholes, seams or other glove imperfections.

Tested according to EN 374-2:2014.

DEGRADATION



Degradation describes a physical deterioration of the glove material caused by contact with a chemical, which may cause the material to shrink or swell, become stiffer or change its structure.

Tested according to EN 374-4:2013.

CHEMICAL HANDLING

How do I select disposable gloves for handling chemicals?



Glove selection should be based on the nature and potential hazard of the substances dealt with as well as the type of exposure. Thin disposable gloves are designed for incidental contact with chemicals providing good barrier and basic chemical protection combined with good tactility and wearing comfort. In general, a higher thickness correlates with higher break through times – but this is only valid for the same material. Nitrile gloves are usually preferred over disposable latex and vinyl gloves because of their enhanced chemical resistance.

If in doubt, please contact the glove manufacturer and ask for assistance in selecting the most appropriate glove.

Which gloves can be used when handling cytotoxic drugs?



Cytotoxic drugs are highly toxic and are increasingly used as therapeutic agents for the treatment of cancer. Appropriate hand protection against chemotherapy drug exposure is vital, which is why gloves should be selected in accordance with the specific type of chemical used. Using a nitrile examination glove may be a good alternative for the handling of cytotoxic drugs, whereas a surgical glove made of natural rubber latex or synthetic polyisoprene latex is recommended for the preparation of chemotherapy drugs. In any case gloves using ASTM D-6978 to test for resistance against chemotherapy drugs should be chosen. Gloves should always be checked for damage before use. Moreover, double donning is recommended to increase protection.

Is it possible to disinfect disposable gloves?



Disposable gloves are not intended for disinfection and re-use (MDR, EN 455); therefore this lies beyond the scope of risk assessment by the manufacturer. Such practice means a health risk for the patient and the healthcare workers (risk of infection, skin damage), since microfine glove lesions and the result of disinfection are both invisible. In legal terms, any person who changes the intended application acts as a manufacturer and thus accepts liability in the case of infections (damages).



REGULATORY



Which are the regulatory requirements for disposable gloves?

Medical devices (MD) are categorized into different classes depending on the range of risk involved for the patient. Relevant classes for disposable gloves are:

- **Class I:** Non-sterile examination gloves
- **Class Is:** Sterile examination gloves
- **Class IIa:** Surgical gloves

The basic standard for single-use medical gloves is the EN 455 series, which defines the requirements for freedom from holes, physical properties, dimensions, test methods for bio-compatibility, labeling requirements and especially also requirements concerning the placement of the expiry date.



MEDICAL DEVICES

93/42/EEC
2007/47/EC



aims to protect the patient

Class I
CE

Class Is/IIa
CE 0123

Applicable standards:

- EN 455



The new Medical Device Regulation (MDR) which was published in May 2017 will replace the EU's current Medical Device Directive (93/42/EEC). **All market participants have to meet the new requirements by May 2020.**

REGULATORY

The two relevant regulatory pillars for disposable gloves in Europe are the Medical Device Directive (MDD) 93/42/EEC and the Directive for Personal Protective Equipment (PPE) REGULATION (EU) 2016/425. The former refers to the protection of patients and healthcare professionals, the latter to the protection of the user of a PPE.



PPEs are divided into three different categories depending on the risk against which they are intended to provide protection:

- ➔ **Category I:**
Protection against minimal risks (simple PPE)
- ➔ **Category II:**
Protection against moderate risks
- ➔ **Category III:**
Protection against lethal hazards or serious and irreversible damage to health (complex PPE)

For gloves labelled as PPE the basic standard is EN 420:2003 + A1 2009, which defines the general requirements for protective gloves, e.g. the contents of the information for users, the safety of the glove material as well as the characteristics of the product (e.g. length, size, etc.). In combination with EN 420:2003 + A1 2009, standard EN ISO 374-1:2016 for protective gloves against chemicals and micro-organisms also applies.

REGULATORY (STANDARDS/PICTOGRAMS)

What do the pictograms and symbols on the glove boxes mean?



Certifies that a product conforms to the applicable EC directives. If a notified body is involved with the conformity assessment procedure, their four digit number is added after the CE sign.



Displays that the product is for single-use only.

Viral Penetration – shows that a glove acts as an effective microbiological barrier in accordance with EN 374-5:2016.



EN 374-1:2016/type A



Type A gloves need to achieve a permeation level of 2 or greater against six of the chemicals listed in EN ISO 374-1 (see table below). As a minimum the six tested chemicals shall be identified by their code letters under the flask pictogram.

EN 374-1:2016/type B



Type B gloves need to achieve a permeation level of 2 or greater against at least three of the chemicals listed in EN ISO 374-1. The tested chemicals shall be identified by their code letter under the flask pictogram.

EN 374-1:2016/type C

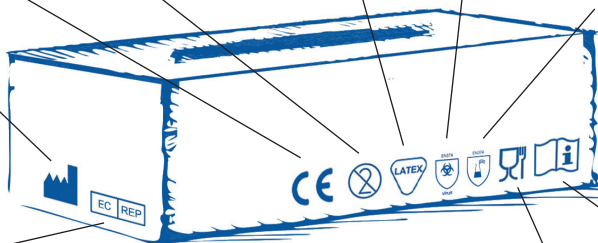


Type C gloves need to achieve at least a permeation level 1 against one of the chemicals listed in EN ISO 374-1.

Points out that the gloves are made from natural latex.



Indicates the manufacturer of the glove.



Indicates that the user instructions have to be read.



Indicates the manufacturer of the glove.

Indicates the manufacturer's batch number so that the lot can be identified.



Displays the "use before" date.



Indicates that the product complies to European Regulation 1935/2004 and applicable provisions, and is suitable for food contact.



Indicates the date of manufacture.



How do I know that a disposable glove is suitable for food contact?

Gloves suitable for food contact may be recognized by the glass and fork symbol which is subject to specific regulations in the EU that govern articles intended to come into contact with food:



1 Framework regulation EC 1935/2004 lays down the general requirements for all materials and articles (e.g. gloves) intended to come into contact with food.

2 Certain materials, such as vinyl, are subject to EU Regulation 10/2011, which defines specific requirements for products containing vinyl that may come into contact with food.

3 Latex and nitrile products are mostly regulated on a national level, for example in Germany via the recommendations of materials for food contact of the Bundesinstitut für Risikobewertung (BfR) or in France by the law "Arrêté du 9 Novembre 1994".



Why are gloves made of vinyl (PVC) not suitable for handling fatty food?

In PVC glove production softeners (plasticizers) are used as one of the main materials besides PVC in order to give the material the necessary elasticity, softness and flexibility. Phthalates are not permanently bound to the PVC polymer, but rather form a leachable element, which is why they show a tendency to migrate into food.

As plasticizers are highly soluble in fats and oils, the migration level of plasticizers in contact with fatty foodstuffs exceeds the limits allowed in EU directives. This is why the use of vinyl gloves should be avoided in contact with fatty foodstuffs.

FOOD HANDLING



Why do gloves for handling food often have a blue or blueish color?

The fact that protective gloves often have a blue color may partly be ascribed to the principle of prevention defined in the HACCP concept (Hazard Analysis and Critical Control Points).

Since there is a risk of parts or even whole gloves possibly being lost when foods are being processed, protective gloves worn when handling foods are often colored in a blue tone.

This is a color that is not found in foods and so is immediately identifiable, thereby minimizing any risk of contamination.































FOOD HANDLING

Which disposable gloves should be used to handle food?



Gloves should basically be selected according to the nature of the activity and food involved. In general it is assumed that in the food industry the direct contact time with one and the same food stuff is less than 10 minutes. Due to the wide spectrum of material properties, Sempermed recommends the use of a powder-free nitrile glove (blue-colored) because it is optimally suited for most requirements in the food sector.

Food Safety Recommendations		Latex	Nitrile	Vinyl
	Liquid Food e.g. honey, eggs			
	Fruits, Vegetables e.g. salad, citrus fruits			
	Alcohol e.g. beer, wine, spirits and other beverages			
	Meat, Sausages			
	Fats e.g. butter, margarine, cheese, cakes, creams			
	Fish, Crustaceans			
	Bakery Products e.g. bread, pastries			



not suitable/not recommended



conditionally suitable/ can be used for short partial contact



suitable for full contact and longer work with the respective food

CONTACT US!

Semperit Investments Asia Pte Ltd • 8 Jurong Town Hall Road • #29-03 to 06 JTC Summit • Singapore 609434 • E-Mail: sempermed@semperitgroup.com • www.sempermed.com

Semperit Technische Produkte Gesellschaft m. b. H. Segment Sempermed
Austria • 1030 Vienna • Modecenterstrasse 22 • Tel.: +43 1 79 777-0 • Fax: +43 1 79 777-630
e-mail: sempermed@semperitgroup.com • www.sempermed.com

Why should I use disposable gloves made by Sempermed?



Sempermed, the largest segment of the Semperit Group, is one of the leading global producers of disposal gloves (surgical and examination gloves for medical purposes, protective gloves for industrial and personal applications). The Sempermed brand has an outstanding track record dating back to 1920 of applying state-of-the-art technologies to offer innovative, high-quality products and solutions.

IMPORTANT NOTE: Please note that the product characteristics are directly dependent on the conditions in which the products are used and the foods with which they come into contact, and that there may be limitations with some materials. In accordance with current European regulations, vinyl gloves in particular are approved only for use with fat-free foods. The latest product information can be found at www.sempermed.com. Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. Semperit does not accept any liability for incorrect use of the gloves. **In case of doubt, obtain expert advice before use.** The information and classification correspond to the latest status prior to printing. Subject to mistakes, printing errors and amendments.

CAUTION: Natural latex can cause allergic reactions, including anaphylactic shock.

