Why should you use Sempermed gloves?

Sempermed is a leading glove manufacturer with over 100 years of experience and a focus on high-quality, skin-friendly and innovative products that help to protect users in many different fields. We continue to be the largest producer of surgical gloves in Europe thanks to our R&D efforts, longstanding manufacturing expertise and committed customer service. And in our state-of-the-art manufacturing facilities in Kamunting, Malaysia, we produce a wide range of examination and personal protective gloves for many different purposes.

sempermed®
YOUR GLOBAL GLOVE EXPERT

Contact us

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29 – 03 to 06 The JTC Summit,
Singapore 609434, Singapore
Tel.: +65 6274 4861 · Fax.: +65 6274 6977

Sempermed Europe GmbH
Am Belvedere 10,
A-1100 Vienna, Austria
Tel.: +43 1 79 777-0 · Fax: +43 1 79 777-630

sempermed@semperitgroup.com · www.sempermed.com

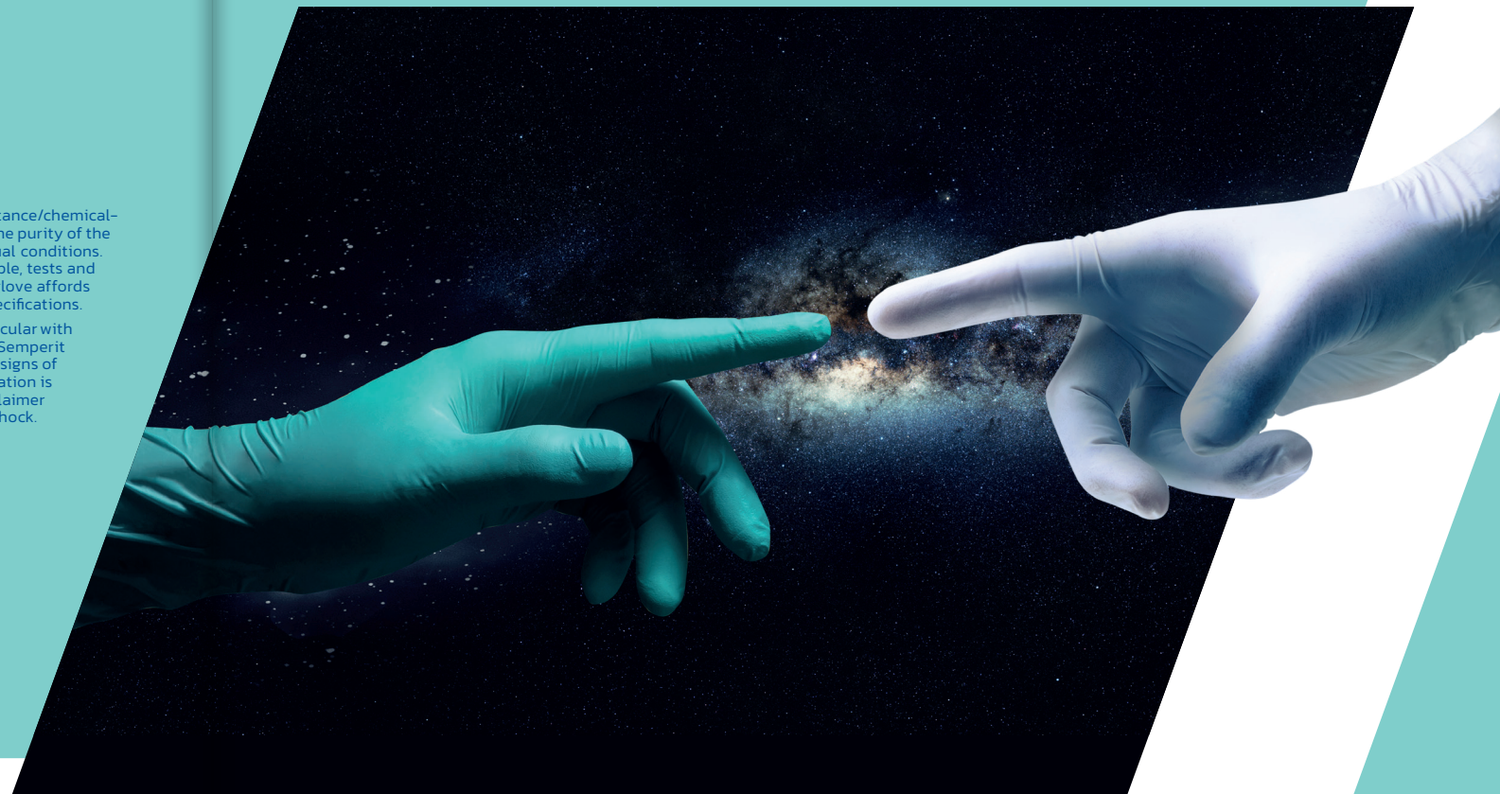
Version 01 10/2022 DM203030Z

sempermed®
YOUR GLOBAL GLOVE EXPERT

THE WORLD OF DISPOSABLE GLOVES

COMPACT GUIDE

100+ YEARS
- EST. 1920 -
sempermed®
YOUR GLOBAL GLOVE EXPERT™



ABOUT GLOVES

What are disposable gloves and why are they used?

A single-use glove, commonly made from natural or synthetic rubber, covers the whole hand and can be used to protect the wearer against harmful environmental influences. As the name implies, single-use gloves, also referred to as disposable gloves, are designed for single use only and should be disposed of immediately after use. For example, in healthcare, caregivers wear gloves to protect themselves and patients from infections.

Which types of disposable gloves exist?
Disposable gloves may vary in terms of:

Material

The most common raw materials used in the production of disposable gloves are natural rubber latex (NR), nitrile butadiene latex (NBR) and PVC/softener paste (vinyl).

Size and shape

Disposable examination and protective gloves are usually available in different sizes (from XS to XL) and can be worn on either hand due to their ambidextrous shape, whereas gloves where better fit is necessary (e.g. surgical gloves) are offered in a higher variety of sizes and are in many cases anatomically shaped.

Inner treatment

Disposable gloves may be powdered or powder-free. While powdered gloves are easier to don even with sweaty hands, powder-free gloves are generally considered more skin-friendly since they usually contain fewer chemical residues and water-soluble proteins.

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.

Texture

Depending on what a glove is used for, different textures are available, ranging from smooth to fingertip- and fully textured.

Colour

Disposable gloves come in various colours, depending on the intended application or simply colour preference.

MATERIALS

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

Latex – the 'classic' glove material

Latex gloves are made of natural rubber (NR) latex, which offers good resistance against many acids and alkalis. However, they are permeable by many solvents. Thanks to both high elongation and low modulus (stiffness of the material), latex gloves are very comfortable to wear. They generally offer the best fit and feel. A disadvantage of natural latex is that its natural proteins can cause or trigger latex allergies.

Nitrile – the 'allrounder' glove material

Nitrile gloves are made of nitrile butadiene rubber (NBR). This synthetic material is a suitable alternative for people with a latex allergy – or those who seek to prevent an allergy. Another advantage is the better overall chemical resistance, to both inorganic and many organic substances. They are versatile and can be used in many different applications, ranging from medical use to food contact and industrial use.

Polyisoprene – latex properties without latex allergies

These synthetic gloves offer the same physical properties as latex gloves: high elasticity and tear resistance, while fully avoiding the risk of a latex allergy. More commonly used in surgical gloves, this material enables users to continue wearing gloves despite having a latex allergy. An increasing number of healthcare institutions switch to polyisoprene as a precautionary measure to prevent new allergies.

Vinyl – the skin-friendly alternative

Vinyl gloves are an economical alternative whenever mechanical and chemical resistance are less important. The skin-friendly material is suitable for users suffering from a latex or accelerator allergy. However, the use of plasticisers in the production makes the gloves unsuitable for handling fats and fatty foodstuffs. Vinyl gloves are used in nursing, geriatric care, professional cleaning & hygiene.

Which glove material should I choose?

Individuals may perceive the material properties of latex, nitrile, polyisoprene and vinyl differently. The following comparison provides a general overview and summarises the main material characteristics to help you choose the right type of glove.

	Latex	Nitrile	Nitrile accelerator free	PI Polyisoprene	PI UV Polyisoprene UV	Vinyl
Comfort	✓✓	✓	✓	✓✓	✓✓	✗
Elasticity	✓✓	✓	✓	✓✓	✓✓	✗
Grip/Tactility	✓✓	✓✓	✓✓	✓✓	✓✓	✓
Tear resistancea	✓✓	✓✓	✓✓	✓✓	✓✓	✗
Elongation	800 %*	600 %*	600 %*	800 %*	1000 %*	300 %*
Puncture resistance	✓	✓✓	✓✓	✓	✓	✗
Chemical resistance	✓	✓✓	✓✓	✓	✓	✗
Latex proteins	✗ present	✓ not present	✓ not present	✓ not present	✓ not present	✓ not present
Accelerators	✗ present	✗ typically present	✓ not present	✗ present	✓ not present	✓ not present
Plasticisers	✓ not present	✓ not present	✓ not present	✓ not present	✓ not present	✓ not present

✓✓ Highly recommended ✓ Recommended ✗ Not recommended * typical material elongation

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 are among the main reasons for allergic reactions towards disposable gloves. An allergy to natural latex proteins is a so-called immediate type (Type I, IgE-mediated) allergy. It is often manifested as full-body reaction (delocalised) and can lead in severe cases to an anaphylactic shock. A reaction to specific chemicals used in the production process (e.g. vulcanisation accelerators) is a so-called delayed-type hypersensitivity (Type IV, T-cell mediated) and often manifests itself as contact dermatitis.

Do latex gloves contain water soluble proteins?

Powder-free latex gloves undergo an extensive leaching and washing process to ensure that the level of leachable proteins is as low as possible. However, for technical reasons, it is not possible to completely eliminate the allergenic proteins, thus a small amount will remain in the glove. Due to the uncertainties of the test method, glove manufacturers cannot claim a protein level of less than 50 µg/g.* The primary packaging must clearly indicate that the glove contains natural rubber latex and show a warning that it may lead to allergic reactions.

** According to EN 455-3*

How can you prevent an allergic reaction to latex?

An allergic reaction due to a latex allergy can be prevented by using latex-free gloves made from nitrile, polyisoprene or PVC. In addition, consistent skin care, which includes drying your hands properly after washing them and applying lotion regularly, can further help to prevent an allergic reaction.

QUALITY INDICATORS

How can you tell if a disposable glove is a quality product?

A low AQL = freedom from holes

The AQL (Acceptable Quality Limit) determines how many defective units are allowed in a batch of manufactured products as assessed by testing a small (randomly sampled) portion. This method of testing follows EN ISO 2859-1, which was developed specifically for products where any testing of samples would lead to their destruction. A lower AQL level corresponds to a more stringent release testing, and thus a potentially lower defect rate. In Europe, a maximum AQL of 1.5 is required for protective gloves applying to complex risks (EN ISO 374-1), for medical examination gloves a maximum AQL of 1.5 (EN 455-1) is required and for surgical gloves an AQL of 0.65 (EN 455-1) is required. For less critical applications (e.g. protective gloves against minimal risks), an AQL level of 2.5 or 4.0 may be sufficient.

Force at break – tensile strength

Even under extreme conditions, disposable gloves have to offer adequate safety. Therefore, the physical properties are a critical parameter to assess the quality of disposable gloves. The force at break, most notably, is defined as the maximum force (in Newton) that a test sample can withstand before it breaks. The European standard for medical gloves (EN 455-2) prescribes a force at break (median) of ≥ 6 Newton for examination gloves made from natural (NR) or synthetic rubber (NBR), ≥ 3.6 Newton for gloves made from thermo-plastic materials (e.g. PVC) and ≥ 9 Newton for surgical gloves.

Weight ≠ quality

Glove users may perceive a glove to be of higher quality if it feels heavier, but this is not necessarily true. Many manufacturers use fillers, which tend to be heavier than polymers, to reduce their costs. The moderate use of filler is common in the glove industry and does not have a negative impact on glove properties, whereas the excessive use of fillers deteriorates a glove's quality. The raw materials used, specific formulations, manufacturing process and the quality inspection system can also affect the glove quality.

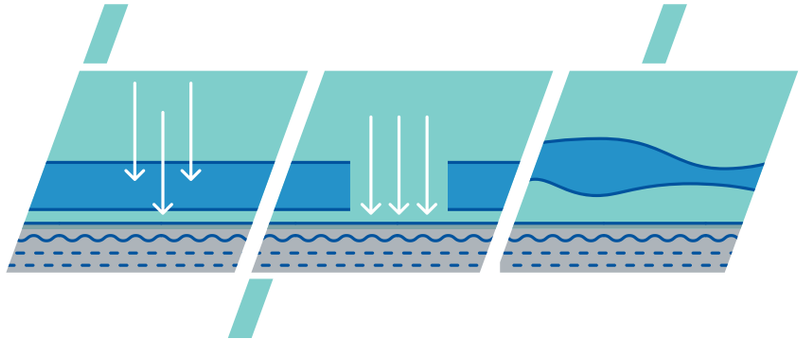
What do permeation, penetration and degradation mean?

Permeation

Permeation describes the process in which a chemical diffuses and moves through intact glove material. It is usually indicated by the breakthrough time, meaning the time it takes a chemical to move completely through the material. It is primarily a property of the main glove material (e.g. NR vs. NBR).
Tested according to EN 16523-1.

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. Like permeation, it is mainly related to the material of the (intact) glove.
Degradation is tested according to ISO 374-4.



All three terms (Permeation, Degradation & Penetration) describe factors that affect the protection against chemicals.

Penetration

Penetration refers to the process in which a chemical moves on a non-molecular level through pinholes, tears or other glove imperfections. It is closely linked to the AQL.
Tested according to EN ISO 374-2.

HANDLING CHEMICALS

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 breakthrough times – when comparing gloves made from the same material. Nitrile gloves are usually preferred over disposable latex and vinyl gloves because of their enhanced chemical resistance.
Please consult our chemical resistance lists to find suitable gloves:

Is it possible to disinfect disposable gloves?

Disposable gloves are not intended for disinfection and re-use (Medical Device Regulation (EU) 2017/745, EN 455); therefore, this lies beyond the scope of risk assessment by the manufacturer. Such practice may bring a health risk for patients and 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 of a disposable gloves assumes liability in case of any infections (damages).

Which gloves can be used to handle cytotoxic drugs?

Chemotherapy 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 option for the handling of most 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, the gloves used should be tested according to ASTM D6978 for their resistance against the relevant chemotherapy drugs. Gloves must always be checked for damage before use.

REGULATORY REQUIREMENTS

What are the regulatory requirements for disposable gloves?

The two relevant regulatory pillars for disposable gloves in Europe are the Medical Device Regulation or MDR (EU) 2017/745, which replaces the MDD, and the Personal Protective Equipment Regulation or PPE-R (EU) 2016/425.
The former refers to the protection of patients and healthcare professionals using medical devices, the latter to the protection of the user of a PPE.

AIMS TO PROTECT THE PATIENT

The ***European Medical Device Regulation*** was published in May 2017 and became binding in May 2021 for non-sterile examination gloves. While the Medical Device Directive 93/42/EEC puts the responsibilities of manufacturers in focus, the new MDR expands the spectrum and considers additional market participants. These can be either a manufacturer, an authorised representative, an importer, a distributor or a person placing procedure packs („kit packs") on the market. Sempermed is currently in the transition of changing their surgical and sterile examination glove portfolio from MDD to MDR.

Medical devices (MD) are categorised into different risk classes depending on the intended purpose of the device. For gloves, the following classes are relevant:

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

Medical devices → **MDR (EU) 2017/745** → **Class I** CE 0123 / **Class Is/IIa** CE 0123 → **Applicable standards**: *EN 455*

The basic standard for single-use medical gloves is the EN 455-series, which defines the requirements for freedom from holes, physical properties, dimensions, requirements for biological safety, real time aging, and labelling requirements such as the placement of the expiry date on the packaging.

AIMS TO PROTECT THE USER

Personal Protective Equipment (PPE) is 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)

Personal Protective Equipment → **Regulation (EU) 2016/425** → **Class I** CE minimal risk / **Class III** CE 2777 (SATRA) or CE 0534 (OETI) → **Applicable standards**: *EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN ISO 21420 (former EN 420), EN 16523-1*

For gloves labelled as PPE the basic standard is EN ISO 21420 (formerly EN 420), 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 ISO 21420, standard series EN ISO 374 for protective gloves against chemicals and microorganisms also applies.

REGULATORY REQUIREMENTS

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

LATEX — Points out that the gloves are made from natural latex.

Displays that the product is for single-use only.

Indicates the manufacturer of the glove.

Displays the "use before" date.

Indicates the date of manufacture.

Indicates that the user instructions have to be read.

CE — 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.

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

EC REP — Indicates the EC Representative of the glove/product.

MD — Shows that the product is certified as medical device according to MDR (EU) 2017/745.

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

EN 374

virus

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

ISO 374-1/ type A

U V W X Y Z

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

ISO 374-1/ type B

X Y Z

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.

ISO 374-1/ 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.

Please contact us for more information on gloves, their applications and applicable standards:
sempermed@semperitgroup.com

FOOD HANDLING

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

Gloves suitable for food contact may be recognised 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 the specific Regulation EU 10/2011, which defines requirements for plastic products (and thus vinyl gloves) that may come into contact with food.
3. Non-PVC gloves are mostly regulated on a national level, for example in Germany via the recommendations of materials for food contact of the German "BfR Recommendation XXI" or in France by the law "Arrete du 5 aout 2020".

FOOD HANDLING

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

In PVC glove production, softeners (plasticisers) are used as one of the main materials besides PVC 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 (fatty) food.

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

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

This fact may partly be ascribed to the principle of prevention defined in the HACCP concept (Hazard Analysis and Critical Control Points).

To minimise the risk of parts or even whole gloves possibly being lost when foods are being processed, protective gloves worn for this application are often coloured in a specific blue tone. This colour is seldomly found in foods thus making potential glove pieces easy to spot.

Which glove materials are most suitable for handling certain foods?

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 food stuff is less than 10 minutes. Due to the wide spectrum of material properties, Sempermed recommends the use of a blue powder-free nitrile glove because it is optimally suited for most requirements in the food industry.

	Liquid food	Fruits, Vegetables	Alcohol	Meat, Sausages	Seafood	Fats	Baked goods
	e.g. eggs, honey	e.g. salad, citrus fruits	e.g. beer, wine, spirits			e.g. butter, margarine, cheese, cakes	e.g. bread, pastries
Latex	✓	✓	✓	✓	✓	✓	✓
Nitrile	✓	✓	✓	✓	✓	✓	✓
Vinyl	✓	✓	✓	✓	✓	✓	✓

✓ not suitable/ not recommended

✓ conditionally suitable/ can be used for short partial contact

✓ suitable for full contact and longer work with the respective food