



## Sempercure nitrile skin<sup>2</sup> - FAQs

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### 1) What information can be found on the PACKAGE?

#### 1.1) - What does the CE marking on the package stand for?

The CE marking on a product certifies that it complies with an EU Directive and thus may be placed on the market in the European Union.

The directive applying to **medical examination gloves** is the Medical Device Directive (93/42/EEC updated by 2007/47/EC). This Directive precisely allocates the products to several usage classes. Examination gloves fall under Class 1: These are non-sterile products invading into natural body orifices (mouth, ear, nose etc.) which are “temporarily” used on the patient (by “temporarily” the Directive understands a continuous use of a maximum of 60 minutes).

In order to depict the usage class, it is specified after the CE marking on the package of the **Sempercure nitrile skin<sup>2</sup>**:



The directive applying to **personal protective equipment** is Directive 89/686/EEC.

**Sempercure nitrile skin<sup>2</sup>** is labelled as personal protective equipment for minimal risks and thus – apart from its core function as medical examination glove – it is also suitable e.g. for cleaning with diluted detergents.

Instructions for using the product are located on the bottom of the package (s.1.5.). Information on the resistance to chemical substances is also given on the package (s.1.2.).

In order to illustrate that **both Directives are complied with**, these are specified next to the pictograms on the sides of the package of the **Sempercure nitrile skin<sup>2</sup>**:

MEDICAL	93/42/EEC
PPE	89/686/EEC

A CE marking on the package certifies that all the Directives specified on the product are complied with. Although the **Sempercure nitrile skin<sup>2</sup>** meets both Directives, there are, therefore, no different or separate CE markings for medical product and personal protective equipment on the package, as this is not permitted.

**1.2) Resistance to chemical substances according to EN 374-3**

On the package sides of the **Sempercare nitrile skin<sup>2</sup>** certain chemicals are listed which are frequently encountered in medical environments. The resistance of the **Sempercare nitrile skin<sup>2</sup>** against these substances has been tested according to EN 374-3.

<b>RESISTANCE TO PERMEATION BY CHEMICALS</b> (tested according to EN 374-3)	✓
<b>SODIUM HYDROXID 40%</b>	level 6
<b>HYDROCHLORIC ACID 36%</b>	level 1
<b>ETHANOL 70%</b>	splash protection
<b>ISOPROPYL ALCOHOL 70%</b>	splash protection
> 10 min.,: LEVEL 1 • > 30 min.,: LEVEL 2 • > 60 min.,: LEVEL 3 • >120 min.,: LEVEL 4 • > 240 min.,: LEVEL 5 • > 480 min.,: LEVEL 6	

**1.3) Resistance to blood born pathogens**

Resistance to blood born pathogens is tested according to the US Standard ASTM F 1671 as there is no respective European standard. **Sempercare nitrile skin<sup>2</sup>** has successfully passed this test, a certificate can be provided on demand.

<b>RESISTANCE TO BLOOD BORN PATHOGENS</b> (ASTM F 1671)	✓
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**1.4) What do the pictograms on the package mean?**

The image shows a row of five pictograms on a light blue background. From left to right: 1. A fork and knife icon with the text 'single-use only' below it. 2. A person icon with a diagonal slash through it. 3. A beaker icon with a question mark inside, labeled 'EN 374' above it. 4. A biohazard symbol, labeled 'EN 374' above it. 5. A shield icon with a question mark inside, labeled 'EN 374' above it. Five callout boxes with lines pointing to each pictogram provide explanations:

- Callout 1:** Sempercare nitrile skin<sup>2</sup> is suitable for the contact with foodstuffs.
- Callout 2:** Symbol for „Single-use only!“. A comprehensive statement on this topic is available on request. Examination gloves must not be reused!
- Callout 3:** Beaker symbol for impermeable protective gloves with low resistance to chemical substances.
- Callout 4:** The symbol “protection against penetration by micro-organisms” may be applied to protective gloves complying with a pinhole rate of max. AQL 1.5.
- Callout 5:** (This callout box is empty in the image).

1.5) Instructions for use

**[en]** Examination gloves and disposable protective gloves for minimal risks, made of nitrile rubber (NBR), powder-free, non-sterile. Ambidextrous. Comply with Directive 93/42 EEC, EN 455, PPE 89/686/EEC, EN 420, EN 374 (length deviating as examination gloves also 240+/-5mm). Free from natural latex. Synthetic co-polymer. Store in dry and dark place, in original package, at 10° – 30°C. Protect from ozone. Dispose of according to applicable regulations. **The product contains dithiocarbamate and zinc-mercaptobenzothiazolate – do not use if sensitive to these substances. For single use only. Check for damages before use, do not use damaged gloves.**

## 2) How does the Sempercure nitrile skin<sup>2</sup> DIFFER from the SEMPERCARE NITRILE?

Apart from the glove's colour (lavender blue [Sempercure nitrile skin<sup>2</sup>](#) vs. blue Sempercure Nitrile) the [Sempercure nitrile skin<sup>2</sup>](#) shows the following differences:

Advantages:

- superior **tactile sensitivity**
- due to its optimised wall thickness it is often felt to be **more comfortable**
- also free from natural rubber latex – at a **cheaper price** than the Sempercure Nitrile

Limitations:

- for high mechanical stress or the administration of cytotoxics we recommend the thicker Sempercure Nitrile



<b>viral protection</b>	✓ yes	✓ yes
<b>pinholes AQL</b>	1,5	1,5
<b>mechanical stress tolerance</b>	weaker	better
<b>wall thickness</b>	superior sensitivity	thicker
<b>chemical protection</b>	basic (nonhazardous)	better (cytotoxics)
<b>cost</b>	advantageous	"all-round" glove
<b>pack size</b>	200	100 or 200

## 3) How does the Sempercure nitrile skin<sup>2</sup> DIFFER from RIVAL PRODUCTS?

Note: part of these issues depend on the impression of the user and on the rival product, but this list has compiled aspects which should be considered in the sales talk:

[Sempercure nitrile skin<sup>2</sup>](#) offers

- excellent **tactile sensitivity** (although some rival products show a comparably thin wall thickness on the palm, the finger tips however are comparatively thick, which reduces their tactile sensitivity)
- **high wearing comfort** (feedback from user surveys referring to rival products – comfortable, easy to don, less transpiration)
- certified **protection against blood born pathogens**
- **neutral smell** (some rival products have a very aggressive smell)
- **dual labelling** as medical product *and* personal protective equipment, therefore it can also be used for tasks which obligatorily require personal protective equipment (whether the protection is sufficient depends on the task); thus it is not necessary to change between medical product and personal protective equipment
- dispenser fits well into **wall holders** (feedback from user surveys: some rival products, mostly in 100-pcs. containers, move too much)
- 200-pcs. package: **less handling / refilling, saves storage space, less packaging waste – environmentally friendly**
- certified for contact with **foodstuffs**

**4) What does „DUAL LABELLING“ as medical product and personal protective equipment (PPE) mean?**

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The marking as medical product\* *and* personal protective equipment\* is also referred to as dual labelling and has been possible in the EU since March 2010.

It offers hospitals the advantage of being able to use the correspondingly labelled product in both areas of application. As the declaration of conformity contains both Directives, the hospital's responsible purchaser also receives an official certification / safeguard for both uses.

Sempercare nitrile skin<sup>2</sup> is dual labelled.

The thus expanded applications (medical product & personal protective equipment) are in case of the Sempercare nitrile skin<sup>2</sup> further complemented by its certified use in contact with foodstuffs (hospital kitchen).

\* for further information on areas of application see 1.1.

**5) Has the Sempercare nitrile skin<sup>2</sup> been tested for RESISTANCE TO BLOOD BORN PATHOGENS?  
Does the glove offer protection against HIV?**

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Yes, the Sempercare nitrile skin<sup>2</sup> has been tested for resistance to blood born pathogens according to ASTM F 1761. The material is resistant to blood born pathogens according to this Standard, as long as the glove is not perforated (holes or fissures) and the barrier protection is not impaired by other high stress. This also applies to HIV.