



**EN – Instructions for use**  
**Examination gloves – Single use**






**Use:** These gloves are basically designed to protect your hands against micro-organisms (bacteria, mold, viruses) and chemical risks. These gloves are reserved for professional use.

**Indication:** Protecting the user and patient during treatment.

**Composition:** Some gloves are liable to contain components which may be a potential cause of allergic reactions seen in some susceptible patients who may develop a skin irritation and/or contact dermatitis. In the event of an allergic reaction, you must consult a doctor. For more information, please do not hesitate to contact Euromedis.

**Technical specifications:**

- Type I medical device, PPE for protection against category III risks
- Single use, non-sterile device.

| <br><b>PPE 2777</b> | <p>Type I device as per European Directive 93/42/EEC on medical devices and new European Regulation 2017/745.</p> <p>PPE for protection against category III risks as per European Regulation 2016/425, following evaluation for compliance conducted by registered body SATRA Europe (CE 2777)</p>  |                              |     |      |      |      |   |   |                                  |     |     |     |      |      |      |
|--|--|------------------------------|-----|------|------|------|---|---|----------------------------------|-----|-----|-----|------|------|------|
|                     | <p><b>EN ISO 21420 : 2020</b><br/>         Read the instructions before use.</p>   |                              |     |      |      |      |   |   |                                  |     |     |     |      |      |      |
|                   | <p><b>EN ISO 374-1: 2016 + A1:2018 /Type A, B or C/J K L O P S T:</b> Protection against chemical risks.</p> <p><b>Type A:</b> penetration time of more than 30 minutes for at least six chemical substances listed in the standard</p> <p><b>Type B:</b> penetration time of more than 30 minutes for at least three chemical substances listed in the standard</p> <p><b>Type C:</b> penetration time of more than 10 minutes for at least one chemical substances listed in the standard (no code below the symbol)</p> <p>J: n-heptane, K: sodium hydroxide 40%, L: sulfuric acid 96%, O: ammonia 25%; P: hydrogen peroxide 30%, S: hydrofluoric acid 40%, T: formaldehyde 37%.</p> <p>Permeation levels are based on breakthrough times as follows:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Permeation performance level</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>6</th> </tr> </thead> <tbody> <tr> <td>Measured breakthrough time (min)</td> <td>&gt;10</td> <td>&gt;30</td> <td>&gt;60</td> <td>&gt;120</td> <td>&gt;240</td> <td>&gt;480</td> </tr> </tbody> </table> | Permeation performance level | 1   | 2    | 3    | 4    | 5 | 6 | Measured breakthrough time (min) | >10 | >30 | >60 | >120 | >240 | >480 |
| Permeation performance level   | 1  | 2                            | 3   | 4    | 5    | 6    |   |   |                                  |     |     |     |      |      |      |
| Measured breakthrough time (min)   | >10  | >30                          | >60 | >120 | >240 | >480 |   |   |                                  |     |     |     |      |      |      |
| <br><b>VIRUS</b>  | <p><b>EN ISO 374-5: 2016 / VIRUS</b><br/>         Protection against bacteria, fungi and viruses</p>   |                              |     |      |      |      |   |   |                                  |     |     |     |      |      |      |
|                   | <p>Suitable for use with food.<br/>         Certified compliant with European Regulations 1935/2004 and 10/2011</p>  |                              |     |      |      |      |   |   |                                  |     |     |     |      |      |      |

**EU TYPE EXAMINATION PERFORMED BY :**

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**SATRA Technology Europe is also responsible for the ongoing conformity**

**Caution:**

Chemical resistance data was obtained following evaluation under laboratory conditions on samples taken only from the palm area (except in cases where the glove is equal to or over 400 mm – where the cuff is tested also) and relating only to those chemical substances tested. Results may vary with certain mixtures of chemicals. EN 374-4: 2019 Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. This information does not reflect the actual duration in the workplace and the differentiation between mixtures and pure chemicals. Penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. Please ensure that you use gloves that are suited to the task. Conditions in the workplace (temperature, abrasion and degradation) may differ in relation to the test type. During use, the ability of these gloves to resist a chemical substance is liable to be reduced due to an alteration in their physical properties. Movements, snagging, friction and degradation caused by exposure to the chemical substance may significantly reduce real protection time. When using corrosive chemical substances, degradation of the gloves turns out to be the priority factor when choosing gloves that are resistant to chemical substances. Data for permeation by chemical substances as per EN 374-1 standard: 2016 and data for degradation as per EN 374-4 standard: 2019 are available on the packaging. Declarations of conformity are available on website: [www.laboratoires-euromedis.fr](http://www.laboratoires-euromedis.fr). Any complaint on glove must be send to [qualite@euromedis.fr](mailto:qualite@euromedis.fr)

**Instructions for use:**

Choose an appropriate size. The gloves are ambidextrous; they can be worn on either hand. Insert five-finger into the cuff and pull the cuff over the wrist as far as they will go. Check for a secure fit around the finger and palm. The cuff should fit snugly around the wrist. To achieve the desired level of protection, this glove may be used along with other PPE or protective medical devices (suit, gown, safety shoes, protective respiratory device, etc.)

Particular precautions for applying and removing protective equipment may be required depending on the area of use (e.g. double gloving).

To doff gloves, grasp the outside of the glove near the wrist; peel the gloves away from the hand, turning it inside out. Hold it in the opposite gloved hand. Slide an ungloved finger under the wrist of the remaining glove being careful not to touch the outside of the glove. Pell the remaining glove off from the inside creating a “bag” containing both gloves. Discard properly (see **Disposal**)

**Precautions for use:**

- Do not open the box with a sharp object.
- Before use, check that the gloves are intact (not perforated or torn). If the gloves tear or become perforated during use, discard them. If in doubt, do not use them and take a new pair.
- This glove does not protect against mechanical risks or ionizing radiation. Do not use these gloves inside a containment enclosure. This glove does not protect against cutting. Use sharp object with care.
- Do not expose these gloves to a naked flame.
- Use of this device in combination with other PPE of a higher class does not increase the scope of application of this device. The user alone is responsible for choosing the right combination and adaptation of these gloves with other equipment, along with the period during which they may be worn depending on the task to be performed, the level of protection required and the level of comfort required by the user.
- All gloves suitable for use with food are not necessarily suitable for all foodstuffs. Some gloves may exhibit excessive migration into some types of foodstuff. To find out which restrictions apply and which specific foodstuffs these gloves are suitable for, please contact Euromedis.
- Any serious incident connected to the use of this device must be notified to the manufacturer and to the competent authorities in the member state in which the user is based.

**Storage and period of use**

Store these gloves in their original packaging, protected from humidity, sunlight and other sources of light. Store these gloves for the period and at the temperature stated on the packaging. Do not use these gloves beyond the expiry date stated on the packaging.

**Disposal**

Depending on the area of use, the user must comply with current national regulations concerning the device and its packaging. These gloves are single-use and are not designed to be washed or reused. They must be discarded after use.