

INSTRUCTION FOR USE OF PERSONAL PROTECTIVE EQUIPMENT

santex® powdered
RD11257001-05(1573)

The instruction below should be used in conjunction with detailed information on the packaging.

Short description of the product

Examination and protective gloves, latex, powdered, for single use, non-sterile


Full description of the product

Reference number : RD11257001-05(1573)
Raw material : natural rubber latex
Cuff : beaded
Colour : creamy
Shape : ambidextrous, fitting to the right and left hand
Size range : XS (5-6), S (6-7), M (7-8), L (8-9), XL (9-10)
Quantity in packaging : 100 pcs. by weight
Shelf life : 5 years (from the date of manufacturing)

Storage instructions

It is recommended to store the gloves in dry place, in the temperature of 10-30°C and to protect them against direct sunlight.
Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone.
Do not keep in direct vicinity of solvents, oils, fuels and lubricants.

Food contact

Gloves are marked with food contact symbol  and comply with the requirements of Regulation (EU) No 10/2011, European Regulation (EC) No 1935/2004 and with Regulation (EC) No 2023/2006 on Good Manufacturing Practice. Gloves are suitable for handling food, except for acidic, and have been tested for Overall Migration Test acc. EN 1186:

| Extraction conditions (tested for 10 min in 40°C) | Analysis results [mg/dm ²] | Test Result (limit < 10 mg/dm ²) |
|---|--|--|
| 10% Ethanol | 2.6 | Pass |
| 3% Acetic acid | 33.0 | Failed |
| DI Water | 2.4 | Pass |

MD classification & compliance

Gloves are classified as class I according to Annex VIII of the Regulation (EU) 2017/745 and comply to standards:

EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN ISO 15223-1:2021, EN 1041:2008+A1:2013.

PPE classification & compliance

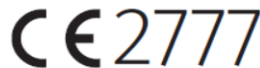
Gloves are category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 and comply to standards:

EN 420:2003+A1:2009, EN ISO 374-1:2016, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN 374-4:2013, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B) and on-going conformity (Module D):

Satra Technology Europe Ltd

Bracetown Business Park,
Clonee, Dublin 15,
Dublin, Ireland



Declaration of Conformity and this instruction for use can be found under below web address: <https://mercatormedical.eu>

Intended use

These are non-sterile examination and protective gloves for single use, intended for use in medical field to: protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling medical contaminated material. Gloves are classified as Medical Devices Class I and as a Personal Protective Equipment Category III, type C. Gloves designed to protect against substances and mixtures which are hazardous to health and against harmful biological agents. Gloves designed to protect against to chemical risk according with EN ISO 374-1:2016 and microorganism (viruses, bacteria and fungi) risks according with EN ISO 374-5:2016. Their design and labelling corresponds to the requirements of the European Regulation 2017/745 on Medical Device and the European Regulation 2016/425 on Personal Protective Equipment. Gloves should be used solely according to their intended application.

Precautions and indications for use

Dry hands before taking the gloves out from the packaging. Before usage, inspect the gloves for any defect or imperfections. Use at least 1 pair of gloves for one patient and one procedure, these are disposable gloves. Do not let chemical substances get under the gloves through the cuff. If a chemical substance reaches the skin, wash it away immediately with plenty of water. If the gloves get punctured, torn or broken during their use, take them off and put on the new ones. Avoid using gloves dirty in the inside as they may cause irritation leading to skin inflammation or more serious damages.

It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on the temperature, abrasion and degradation. The gloves should not be used in contact with open fire and to protect against any sharp tools. The gloves are not intended for welding, electric shock protection, ionizing radiation or from the effect of hot or cold objects.

The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in case where glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture. This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.

When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.

Gloves are suitable for special purposes as they are examination gloves where risk of wrist injury caused by chemicals is considered to be minimal. Length suitable for tasks that require hand protection. Gloves shorter than minimum lengths required by EN 420 standard. Glove minimum length in accordance to EN 455-2 standard.

Components / hazardous components

Product contains natural rubber latex which may cause allergic reactions including anaphylactic responses. Components used in making gloves may cause allergic reactions in some people. Some gloves may contain components known to be a possible cause of allergy for person allergic to them, who may develop contact irritation and/or allergic reaction. In case of an allergic reaction consult a doctor.

Disposal

Dispose of in accordance with applicable regulations. Used gloves can be contaminated with contagious or other hazardous substances. Gloves should be buried or burned under controlled conditions.








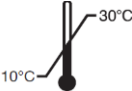















Manufacturer

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www.mercatormedical.eu

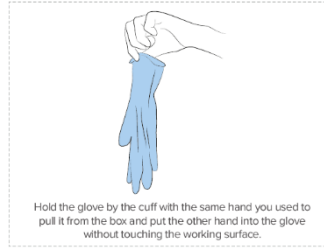
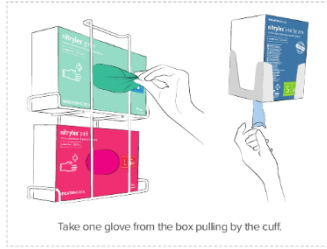
| Permeation performance levels as per EN ISO 374-1:2016 | | |
|--|-------|-------------------------------|
| • Level 1 > 10 min • Level 2 > 30 min • Level 3 > 60 min • Level 4 > 120 min • Level 5 > 240 min • Level 6 > 480 min | | |
| Test results acc. to EN 16523-1:2015+A1:2018 | | EN 374-4:2013 Degradation [%] |
| Chemical | Level | |
| 96% Sulphuric Acid (L) | 1 | 99.4 |
| 65% Nitric Acid (M) | 1 | 53.3 |
| 30% Hydrogen Peroxide (P) | 1 | - 92.5 |

EN 374-4: 2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

| Test acc. to EN ISO 374-2:2019 – Level 2 (ISO 2859) | | Test acc. to EN ISO 374-5:2016 | |
|---|--------|---|------|
| Performance level | AQL | Protection against bacteria & fungi | Pass |
| Level 3 | < 0.65 | Protection against viruses | Pass |
| Level 2 | < 1.5 | EN ISO 374-5:2016 The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. | |
| Level 1 | < 4.0 | | |

| Symbols used on the packaging | | | | | |
|---|--|---|---|---|---|
|  | Medical Device |  | Keep dry |  | Latex gloves |
|  | Personal Protective Equipment |  | Keep away from sunlight |  | Powdered gloves |
|  | Manufacturer |  | Temperature limitation 10-30°C |  | For single use only |
|  | Lot / batch number |  | Keep away from ozone |  | Non-sterile |
|  | Catalogue number |  | Product quality is not ensured if the package is damaged |  | Designed to protect against to chemical risks acc. with EN ISO 374-1 (type C) |
|  | Expiry date |  | Recyclable packaging |  | Designed to protect against microorganisms risks acc. with EN ISO 374-5 |
|  | Date of manufacture |  | Package can be treated as municipal waste |  | Consult instructions for use |
|  | Indicates compliance with the requirements of Ukrainian market |  | Suitable for food contact (for details check the instruction for use) | | |

■ HOW TO PUT THE GLOVES ON?



■ HOW TO TAKE THE GLOVES OFF?

