

**USER`S INSTRUCTION and ADD. INFORMATION FOR USERS
AMBULEX**

Medical gloves and disposable protective gloves made of natural rubber latex (NR), powdered, non sterile, ambidextrous, for single use.

The risk protection level is only met for a new product.

PROPERTIES

Disposable examination gloves, commonly used in health care. They reduce the risk of infection during examinations procedures and contact with contaminated medical material.

The gloves meet the requirements of the Medical Device Regulation (EU) 2017/745 and the standards: EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009.

The gloves meet the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 and the standards: EN ISO 21420:2020, EN ISO 374-1:2016, EN ISO 374-5:2016, ASTM F1671/F1671M-13. They are personal protective equipment of category III and have an EU-type examination certificate issued by an independent entity SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin D15YN2P, Ireland (2777).

Gloves marked with a pictogram  indicating approval for contact with food, comply with the Regulation of the European Parliament and of the Council No. 1935/2004. The gloves have a Health Quality Certificate of the National Institute of Hygiene, which allows them to come into contact with food.

Symbols used on the packaging	
	Batch code
	Manufactured by
	Date of manufacture
	Use by
	Do not use if package is damaged
	Do not reuse
	Consult instructions for use
	Keep away from sunlight

	Keep dry
AQL 1.5	Acceptance quality limit
	For food contact
MD	Medical device

EXPLANATION OF PROTECTION LEVELS

EN ISO 374-5:2016



Protection against microorganisms

The gloves protect against the penetration of bacteria, viruses and fungi.

EN ISO 374-1:2016
Type C



Protection against chemicals

The glove that has a permeation resistance of at least a performance level 1 against a minimum of 1 test chemical listed in EN ISO 374-1 is classified as Type C.

PRECAUTIONS FOR USE

These gloves protect against chemical threats in accordance with the marked values of the protection levels. It should be taken into account that the confirmed level of resistance according to EN 16523-1 does not reflect the actual working conditions, where other factors may influence the protection performance.

Before using the gloves, always check them for possible mechanical damage, e.g. punctures or tears. If in doubt, do not use the gloves, take a new pair. It is recommended that the skin of the hands be thoroughly dry before putting on the gloves. Each time after taking off the gloves, it is recommended to wash your hands thoroughly, dry them and apply care cream. Use min. 1 pair of gloves for one patient and one procedure. Gloves contaminated with blood or body fluids should be disposed of as medical waste. If a chemical substance gets into the skin, it should be washed off immediately with plenty of water and soap. Be careful not to let chemicals enter the gloves through the cuff. Do not use gloves that are dirty inside - they may cause irritation or infections causing dermatitis or more serious ailments. This product contains natural latex, which can cause allergic reactions including anaphylactic reactions. The product contains zinc dithiocarbamate - not to be used in the case of hypersensitivity to these substances. In the event of an allergic reaction, seek medical attention immediately. The reuse is unacceptable - it carries a very high risk of infection of the patient/user.

PACKAGING AND STORAGE CONDITIONS

The gloves are packed by 100 pieces in individual boxes. The boxes with gloves are packed in cartons suitable for transport and storage. The gloves should be stored at a temperature of +5°C to +35°C in

their original packaging, in a dry and dark place. Protect against heat, moisture, strong light and ozone.

SHELF LIFE

With proper storage, the physical properties of the gloves are maintained for a period 5 years from their manufacture. The production date and expiry date are marked on the packaging.

DISPOSAL

Used gloves should be disposed of in accordance with the applicable regulations for medical waste. Gloves contaminated with chemical substances should be disposed of in accordance with the regulations on the given chemical substances.

FINAL REMARKS

A damaged product should be immediately withdrawn from use, because it does not provide the protection declared by the manufacturer, and its continued use may cause additional hazards.

Any serious incident related to the device must be reported to the manufacturer and to the competent authority of the Member State where the user or patient resides.

Date of updating the instruction: 2021/07/15

