

INSTRUCTIONS FOR USE

AMBULEX P


Latex examination gloves, non sterile, powder free, polymer coated.

Disposable product for medical use.

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

CHARACTERISTICS

Disposable examination gloves, having widespread application in health care. Reduce the risk of infection during examinations and procedures, and while having contact with contaminated medical material. The gloves meet the requirements of the Medical Directive 93/42/EEC, EN 455, the Personal Protective Equipment Directive 89/686/EEC, EN 420, EN 374 excluding point 5.3.2, ASTM F1671, ASTM D3578, ASTM D6124, ASTM D5151, ASTM D5712.

Gloves marked with the pictogram  meaning the approval for food contact, are in accordance with the Regulation No. 1935/2004 of the European Parliament and of the Council.

EXPLANATION OF PROTECTION LEVELS



Protection against microorganisms

The glove is considered to be resistant to microorganisms if it has successfully undergone the penetration test (air and/or water leak test) and if it has achieved at least level 2 of the penetration test.

LEVEL	AQL
3	< 0.65
2	< 1.5
1	< 4.0



Protection against chemicals

The glove that has passed the penetration test, but has not obtained a breakthrough time of at least 30 minutes for at least three chemicals from the defined list, is considered a glove with low chemical resistance.

Detailed information concerning the glove chemical resistance is available at your medical representative.

PRECAUTIONS FOR USE

These gloves protect against mechanical and chemical threats according to the marked protection levels. It should be remembered that the confirmed protection level (according to EN 374-3) does not reflect the actual working conditions where other factors may affect the performance of the protection.

Before use, the gloves must always be checked for possible mechanical damage, e.g. holes or tears. If in doubt, do not use these gloves and use a new pair. Before putting on the gloves, it is recommended to precisely dry the hand skin. Every time after taking off the gloves it is recommended to wash hands thoroughly, dry and apply skin care cream. Use at least 1 pair of gloves per a single patient and for one procedure. Gloves contaminated with blood or body fluids should be disposed of as medical waste. If the skin gets into contact with some chemical, it needs to be immediately washed off with plenty of water and soap. Be careful that the chemicals do not penetrate the glove over the cuff. Do not use gloves if dirty inside - they can cause irritations or infections that cause dermatitis or more serious ailments. This product contains dithiocarbamate, zinc-mercaptobenzothiazole and latex, and may cause allergic reactions including anaphylactic shock. Do not use in the case of hypersensitivity to these substances. In the case of an allergic reaction, seek immediate medical attention.

PACKAGING AND STORAGE CONDITIONS

The gloves are packed in individual boxes by 100 pieces. The boxes with gloves are packed in cardboard boxes designed for transport and storage. The gloves should be stored at 10°C to 30°C in the original packaging, in a dry and dark place. Keep away from heat, moisture, strong light and ozone.

SHELF LIFE

With proper storage the physical properties of the gloves are retained for five years from the manufacture. The manufacture and expiry date are given on the packaging.

DISPOSAL

Used gloves should be disposed of in accordance with the valid regulations for this material. Gloves contaminated with chemical substances must be disposed of in accordance with the regulations for the relevant chemicals.

FINAL REMARKS

A damaged product should be immediately disposed of, because it does not provide protection declared by the manufacturer, and its use can cause additional hazards.

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