



NOBAMED Paul Danz AG

NOBAGLOVE®-Latex

REF 905453

Product Description, Intended use, Application

NOBAGLOVE®-Latex are powder-free medical examination gloves, size **L**, and are made of latex. The disposable gloves are tear-resistant, elastic, tight, microbe-resistant, ambidextrous. The slightly rough surface of the glove increases its grip, and the rolled cuffs facilitate donning. The colour of the gloves is white to light yellow. They are used for medical examinations, for diagnostic and therapeutic purposes, for the handling of contaminated medical materials, for protection against contaminations in medicine, health care, or laboratories.

Composition

Latex, ZDBC
No thiurams and urea.

Contra-Indications

NOBAGLOVE®-Latex examination gloves contain natural rubber latex which may cause allergic reactions, including anaphylactic responses.

The product should not be used in the case of a known allergy against the material.

Note

Check for damage before use.
Do not use damaged gloves.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical devices according to directive MDD 93/42/EEC and Regulation MDR (EU) 2017/745

They comply with the requirements of EN 455 parts 1, 2, 3 and 4.

The AQL is 1,5 referring to the imperviousness, in compliance with EN 455-1.

The powder content of all gloves is below the maximum permissible normative value of 2 mg/glove (EN 455-3).

Protein content of all gloves is at the normative value of ≤ 50 ug/g ((EN 455-3).

The product has been tested for protection against chemicals and microorganisms according to EN ISO 21420, EN ISO 374, EN 16523-1 und ISO 16604.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging:	folding box made of cellulose
Secondary packaging:	carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment between +5°C and +40°C, protect from direct solar radiation.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.