



NOBAMED Paul Danz AG

NOBAGLOVE®-steril NITRIL

REF 909204 (as of LOT 135941)

Product Description, Intended use, Application

The single-use, powder-free sterile examination gloves (size XL) are intended for use in non-invasive clinical purpose for protection from cross-contamination for both patient and user. A textured surface in the grip area increases the safe grip.

Composition

Nitrile Butadien Rubber (NBR)
The product is latex-free.

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 Regulatory Requirements, Common Standards

Medical Device according to *MDD 93/42/EEC*, *MDR (EU) 2017/745*.

The examination gloves meet the requirements of EN 455. The AQL is $\leq 1,5$ referring to the imperviousness.

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

Packaging

Primary packaging: paper packaging

Secondary packaging: folding box made of cellulose

Tertiary packaging: carton made of cellulose

Symbols used in labelling

Explanation 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

Dry and dustfree, protect from sunlight.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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.