



NOBAMED Paul Danz AG

NOBAFOL®

REF 904963

Product Description and Purpose

Disposable foil gloves (size L) for simple activities on patients without the need for high tactile accuracy and grip, for general patient care activities and cleaning service. Not for risk areas.

Contra indication

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

Composition

Polyethylene

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 Legal

Requirements

NOBAFOL® is a medical product according to directive MDD 93/42/EEC and the regulation MDR (EU) 2017/745 and is classified as class I, rule 1.

The product is food safe according to Title 21 of CFR 177.1520 "Olefin Polymers" of the FDA

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

It has CE marking and DIN EN ISO 15223-1 labels on all its packaging.

Packaging

Primary packaging: folding box made of cellulose

Secondary packaging: carton made of cellulose

Symbols used in labeling

Explanations at www.nobamed.com



Storage and transportation

To be stored in a dry and dust-free environment

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.