



**NOBAMED Paul Danz AG**

## **NOBAGLOVE®-steril NITRIL**

**REF 909202** (as of LOT 135941)

### **Product Description, Intended use, Application**

The single-use, powder-free sterile examination gloves (size M) 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](http://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.