



**NOBAMED Paul Danz AG**

## **NOBAGLOVE®-Vinyl**

**REF 905354**

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

NOBAGLOVE®-Vinyl are **white-transparent**, powder-free medical examination and protective gloves, **size XL**, made of soft polyvinyl chloride. The non-sterile disposable gloves with a good fit are tear-resistant, elastic, tight, microbe-resistant and ambidextrous. The gloves have a smooth surface. The polymeric inner coating and the rolled cuffs facilitate donning the gloves. They are used for medical examinations, for diagnostic and therapeutic purposes, for the handling of contaminated medical materials, for protection against cross-contamination, in medicine, health care or in laboratories.

### **Composition**

PVC, DINP, DOTP, TXIB, calcium/zinc-stabiliser, polymer  
No DEHP is used  
The product is latex- and accelerator-free

### **Contra-Indications**

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

### **Note**

Depending on working conditions, the actual duration of protection may deviate from the values in the tables.

It is recommended to test the gloves for use in the respective working conditions.

Check for damage before use.

Do not use damaged gloves.

No reprocessing.

Waste disposal in accordance with current regulations.

### **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

Protective gloves according to the PPE Regulation (EU) 2016/425 Category III.

They comply with the requirements of EN 455 parts 1, 2, 3 and 4, and with EN 420, EN 374: parts 1, 2, 4 and 5, and EN 16523-1.

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).

The biocompatibility is tested acc. to DIN EN ISO 10993, the protection against microorganism acc. to EN 374-5

Suitable for food according to EN 1186.

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

### **CE 2797, PPE Regulation (CAT III)**

BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, NL

### **Packaging**

|                      |                                  |
|----------------------|----------------------------------|
| Primary packaging:   | folding box<br>made of cellulose |
| Secondary packaging: | carton made of cellulose         |

## Symbols used in labelling

Explanations 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.

## Medical device class I

EN 455-1: 2000; EN 455-2:2015

EN 455-3: 2015; EN 455-4: 2009

EN 420: 2003+A1:2009

## PPE (CAT III)

EN 374-1: 2016+ A1: 2018

| Permeation levels are based on breakthrough times as follows: |    |    |    |     |     |     |
|---------------------------------------------------------------|----|----|----|-----|-----|-----|
| Level                                                         | 1  | 2  | 3  | 4   | 5   | 6   |
| Min breakthrough times (min)                                  | 10 | 30 | 60 | 120 | 240 | 480 |

  

|                                                                                                                                                                 |                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Test according to EN 16523-1:2015</p> <p>The penetration resistance has been assessed under laboratory condition and relates only to the tested specimen</p> | <p>EN ISO 374-1: 2016/<br/>Type C</p>  <p><b>Sodium hydroxide (K)</b><br/>40 % Level 6</p> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## 374-4: 2013 (Degradation)

| Degradation mean percentage results: |           |                 |
|--------------------------------------|-----------|-----------------|
| Chemical                             | CAS No    | Degradation [%] |
| Sodium hydroxide (K) 40%             | 1310-73-2 | -9.3            |

The degradation level indicates the value from which the effect of the degradation (modification of glove material) through the tested chemical is verifiable.

## EN 374-5: 2016:

| EN ISO 374-5: 2016                    | Level | EN ISO 374-5: 2016                                                                           |
|---------------------------------------|-------|----------------------------------------------------------------------------------------------|
| Protection against bacteria and fungi | Pass  | <br>Virus |
| Protection against virus              | Pass  | Level 2, AQL < 1.5                                                                           |

## EN 374-2: 2014:

| Performance Level | AQL   | Inspection levels |
|-------------------|-------|-------------------|
| Level 3           | <0.65 | G1                |
| Level 2           | <1.5  | G1                |
| Level 1           | <4.0  | S4                |

## 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.