NOBAMED Paul Danz AG

NOBAGLOVE®-Vinyl

REF 905351

Product Description, Intended use, Application

NOBAGLOVE®-Vinyl are **white-transparent,** powder-free medical examination and protective gloves, **size S**, 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)

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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 EB 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

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

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 VIRUS
Protection against bacteria and fungi	Pass	
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.