NOBAMED Paul Danz AG

NOBAGLOVE®-Nitril

REF 905653

Product Description, Intended use, Application

The powder-free blue examination and protective gloves **with longer cuffs (300 mm)**, **size** L, made of nitrile, are tear-resistant, elastic, tight, resistant to microbes, declared chemical-resistant and ambidextrous. NOBAGLOVE-Nitrile are used for medical examinations, for diagnostic and therapeutic purposes, for the handling of contaminated medical materials, for protection against cross-contamination, but also for the handling of chemicals, in medicine, health care or in laboratories.

Composition

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

Contraindications

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 Device according to MDD 93/42/EEC, MDR (EU) 2017/745.
Protective glove 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 ISO 21420, EN 374: parts 1, 2, 4 and 5.

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.

They have been tested in accordance with ASTM D 6978-05 as to the breakthrough detection time of chemotherapeutics, which measures the breakthrough already from 0.01 µg/cm²/min (“Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs”).

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

CE 2777, PPE Regulation (CAT III), SATRA Technology Europe Ltd, Bracetown Business Park, Clonee, Dublin, D15 YN2P, Ireland

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 ISO 20417.

Medical device class I

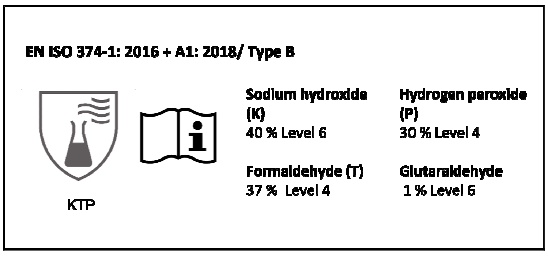
EN 455-1: 2020; EN 455-2:2015
EN 455-3: 2015; EN 455-4: 2009

PPE (CAT III)

EN ISO 21420:2020

EN ISO 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



EN ISO 374-2: 2019:

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

EN ISO 374-4: 2019 (Degradation)

Degradation mean percentage results:		
40 %	Sodium hydroxide (K)	-15 %
37 %	Formaldehyde (T)	3.1 %
30 %	Hydrogen peroxide (P)	9.2 %
1 %	Glutaraldehyde	-4.2 %

Degradation results indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.

EN ISO 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

The penetration resistance has been assessed under laboratory condition and relates only to the tested specimen.

Breakthrough time chemotherapeutics acc. to ASTM D 6978-5

Chemotherapy Drugs and Concentration (Tested for Resistance to permeation by Chemotherapy Drugs as per ASTM D6978-5)	Minimum Breakthrough Detection Time (min)
Carmustine 3.3 mg/ ml (3,300 ppm)	26.8'
Cisplatin 1.0 mg/ ml (1,000 ppm)	>240'
Cyclophosphamide (Cytoxan) 20 mg/ ml (20,000 ppm)	>240'
Dacarbazine (DTIC) 10 mg/ml (10,000 ppm)	> 240'
Doxorubicin Hydrochloride 2.0 mg/ml (2,000)	>240'
Etoposide 20.0 mg/ml (20,000 ppm)	> 240'
Fluorouracil 50.0 mg/ml (50,000 ppm)	>240'
Methotrexate 25 mg/ml (25,000 ppm)	> 240'
Mitomycin C 0.5 mg/ml (500 ppm)	> 240'
Paclitaxel 6.0 mg/ml (6,000 ppm)	> 240'
Thiotepa 10.0 mg/ ml (10000 ppm)	27.8'
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	>240'

We would like to point out that even with an intact glove, a change at least every hour is recommended in the relevant guidelines when used with cytostatic drugs, irrespective of breakthrough times greater than 60 minutes.

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.