NOBAMED Paul Danz AG

NOBAGLOVE®-Nitril ultra

REF 905982

Product Description, Intended use, Application

NOBAGLOVE®-Nitril ultra (≥ 2.2 mil) are powder-free medical examination gloves and protective gloves, **size M,** in a standard minimum 240 mm length**.** They are made of nitrile rubber. The nonsterile, **white** disposable gloves are ambidextrous. They are used for medical examinations, for diagnostic and therapeutic purposes, for the handling of contaminated medical materials, for protection against cross-contaminations, but also for the handling of chemicals, in medicine, health care, or laboratories.

Composition

Nitrile rubber (NBR)
The product contains dithiocarbamates.
The product is latex-free.

Contraindications

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

Notes

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

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 part 1, 2, 3 and 4 and EN 420, EN 374 part 1, 2, 4 and 5.

Suitable for food according to EN 1186.

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 and the protection against microorganisms (viruses, bacteria and fungi) acc. to EN 374-5.

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 ot cellulose
Secondary packaging:	carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com

CE 2777

Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and DIN EN ISO 20417.

Medical device

EN 455-1: 2000; EN 455-2:2015; EN 455-3: 2015; EN 455-4: 2009

Physical Dimensions (EN 455)					
REF	Size	Median Glove Length (mm)	Median Palm Width ± 4 mm	Median Thickness (mm) Palm (center of palm)	Median Thickness (mm) Finger (13 ± 3 mm from tip)
905980	XS	≥ 240	76	Min 0.05	0.08 ± 0.03
905981	S	≥ 240	86	Min 0.05	0.08 ± 0.03
905982	M	≥ 240	98	Min 0.05	0.08 ± 0.03
905983	L	≥ 240	107	Min 0.05	0.08 ± 0.03
905984	XL	≥ 240	115	Min 0.05	0.08 ± 0.03

Physical Properties (EN 455, ASTM D6319)		
Test	Before Aging	After Aging
Median Force at break	≥ 6 N	≥ 6 N
Tensile Strength	≥ 18 MPa	≥ 16 MPa
Elongation	≥ 500 %	≥ 400 %

PPE (CAT III)

EN 420: 2003+A1:2009

EN ISO 374-1: 2016: 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 374-1: 2016 Type B

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 B

KPT

Sodium hydroxide (K) 40 % Level 6

Hydrogen peroxide (P) 30 % Level 2

Formaldehyde (T) 37 % Level 5

EN 374-4:2013

Chemical	CAS No	Degradation
Sodium hydroxide (K) 40%	1310-73-2	-25.7 %
Hydrogen peroxide (P) 30%	7722-84-1	44.8 %
Formaldehyde (T) 37%	50-00-0	-17.1 %

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

EN ISO 374-5: 2016:

EN ISO 374-5: 2016	Level	EN ISO 374-5: 2016
Protection against bacteria and fungi	Pass	 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

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)	15.3‘
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)	46.3‘
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, protected 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.