NOBAMED Paul Danz AG

NOBAGLOVE®-Cytostax

REF 905854

Product Description, Intended use, Application

NOBAGLOVE®-Cytostax are powder-free medical examination gloves and protective gloves, **size XL.** The nonsterile disposable gloves are tear-resistant, elastic, tight, with good grip, microbe-resistant, and ambidextrous. NOBAGLOVE®-Cytostax are anatomically shaped, micro-structured, hypoallergenic, with extra-long rolled cuffs (290 mm). The colour of the gloves is **blue**. They 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 particular cytostatics, in medicine, health care, or laboratories.

Composition

Carboxylated acrylonitrile-butadiene polymer, Auxiliaries: zinc-di-n-dibutyl-dithiocarbamate.

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 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 also with standard ASTM D 6319 and with EN 420, EN 374: parts 1, 2, 4 and 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"), and also regarding the protection against radioactive contamination according to EN 421 (without section 4.3).

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, the protection against microorganism acc. to EN 374-5
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: 2000; EN 455-2:2015;
EN 455-3: 2015; EN 455-4: 2009

PPE (CAT III)
EN 420: 2003+A1:2009

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

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  JKPT	**n-Heptane (J)** Level 3 **Sodium hydroxide (K)** 40 % Level 6 **Hydrogen peroxide (P)** 30 % Level 2 **Formaldehyde (T)** 37 % Level 6

EN ISO 374-2: 2014

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

EN ISO 374-4: 2013 (Degradation)

Chemical	CAS No	Degradation [%]
n-Heptane (J)	142-82-5	33.9
Sodium hydroxide (K) 40%	1310-73-2	-19.9
Hydrogen peroxide (P) 30%	7722 84 1	34.5
Formaldehyde (T) 37%	50-00-0	-11.0

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 421: 2010 (without section 4.3)

EN 421: 2010

Protection against particulate radioactive contamination

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 (3300 ppm)	Not recommended
Cisplatin 1.0 mg/ ml (1000 ppm)	> 240′
Cyclophosphamide (Cytoxan) 20 mg/ ml (20000 ppm)	> 240′
Dacarbazine (DTIC) 10 mg/ml (10000 ppm)	> 240′
Doxorubicin Hydrochloride 2.0 mg/ml (2000)	> 240′
Etoposide (Toposar) 20.0 mg/ml (20000 ppm)	> 240′
Fluorouracil 50.0 mg/ml (50000 ppm)	> 240′
Methotrexate 25 mg/ml (25000 ppm)	> 240′
Mitomycin C 0.5 mg/ml (500 ppm)	> 240′
Paclitaxel (Taxol) 6.0 mg/ml (6000 ppm)	> 240′
Thiotepa 10.0 mg/ ml (10000 ppm)	Not recommended
Vincristine Sulfate 1.0 mg/ml (1000 ppm)	> 240′

Please note that even intact gloves should be changed at least every hour if used with cytostatics, regardless of breakthrough times of more than 60 minutes, according to the relevant directives.

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.