NOBAMED Paul Danz AG

NOBAGLOVE®-NITRIL classic

REF 905564

Product Description and Purpose

The powder-free blue examination and protective gloves, size XL, 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.

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 Legal Requirements, Common Standards

NOBAGLOVE®-Nitril with double function are on the one hand medical devices according to directive MDD 93/42/EEC and Regulation MDR (EU) 2017/745 and are classified as class I, rule 5 products, and on the other hand they are 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 ISO 21420, EN ISO 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 virus imperviousness acc. to ISO 16604.
Suitable for food according to EN 1186.

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

Symbols used in labelling

Explanations at www.nobamed.com

PPE (CAT III)
Medical device class I
EN 455-1: 2000; EN 455-2:2015
EN 455-3: 2015; EN 455-4: 2009
EN ISO 21420: 2020

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

Packaging

Primary packaging: folding box made of cellulose

Secondary packaging: carton made of cellulose

Storage

To be stored in a dry and dust-free environment between +5°C and +40°C, protect from direct solar radiation.

Notified body responsible for EU Type examination and ongoing conformity:
CE 2777, SATRA Technology Bracetown Business Park, Clonee, D15 YN2P, Ireland

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 374-1:2016+A1:2018/Type B

KPT

Sodium Hydroxide 40% (K) Level 6

Hydrogen Peroxide 30% (P) Level 2

Formaldehyde 37% (T) 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: 2019 (Degradation)

Chemical	CAS No	Degradation
Sodium hydroxide (K) 40%	1310-73-2	-20.5 %
Hydrogen peroxide (P) 30%	7722-84-1	3.7 %
Formaldehyde (T) 37%	50-00-0	-18.8 %

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 viruses	Pass	Level 2 AQL < 1.5

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.