NOBAMED Paul Danz AG

NOBAGLOVE®-Nitril ultra

REF 905951

Product Description and Purpose

NOBAGLOVE®-Nitril ultra are powder-free medical examination gloves and protective gloves, **size S (7).** They are made of nitrile rubber. The nonsterile, **blue-purple** 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. They are approved for food contact.

Contra-Indications

No contra-indications known.

The product must not be used if there is a known allergy to one of the below mentioned ingredients.

Composition

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

Normative and Legal Requirements

NOBAGLOVE®-Nitril ultra with double function are on the one hand medical devices according to MPG (Medical Devices Act), Directive 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 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.

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

All packing levels are labelled acc. to DIN EN ISO 15223-1 and EN 1041.

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

Storage

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

The product bears the following symbols and marking

CE 2777

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 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 ISC 374 1: 2016/ ype B KPT	Sodium hydroxide (K) 40 % Level 6 Hydrogen peroxide (P) 30 % Level 2 Formaldehyde (T) 37 % Level 5

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 374-5: 2016:

EN ISO 374-5: 2016	Level	EN ISO 374-5: 2016 V RUS
Protection against bacteria and fungi	Pass	
Protection against virus	Pass	Level 2, AQL < 1.5

374-2: 2014

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

Note
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.