

MEDASEPT S.A.

Instructions for use: Powder-Free Nitrile Gloves

Brand: **medaSEPT NITRILE PREMIER PF**

Ref: MSNPRPF100/MSNPRPF200

Basic UDI-DI: 590173887RDNPFGL

Product:

Nitrile examination and protective gloves, powder free, non-sterile for disposable use

Description of the product:

Raw material:	nitrile
External Surface:	finger textured
Cuff:	beaded
AQL:	1.5
Shape:	ambidextrous
Quantity in packaging:	100 psc. by weight
Size range:	XS (5-6); S (6-7); M (7-8); L (8-9); XL (9-10)
Shelf life:	5 years (from the date of the manufacturing)

Intended use:

Nursing; Medical diagnostics; Dentistry; Veterinary; Research laboratories; Central sterilization room; Pharmacy; Food industry; Gastronomy; Catering; Cosmetology; Hairdressing, non-aggressive household chemicals; Housework; Chores

Diagnostic gloves intended for medical examination, nursing care, therapeutic activities and other activities in the medical environment, designed to protect both the patient, medical personnel and users from infection and contamination.

Classification and compliance:

Gloves are classified as class I according of the Regulation (EU) 2017/745 [MDR] and comply to standards: EN 15223 -1; EN 1041; EN ISO 14971; EN ISO 13485; EN ISO 10993-1;5,10; EN 455 -1;2;3;4.

Gloves are classified as category III Personal Protective Equipment as per Annex I of the Regulation 2016/425 [PPE] and comply to standards : EN 420:2003+A1:2009, EN ISO 374-1:2016, EN 374-2:2014, EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016

Food contact:

Gloves approved for contact with food. They comply with Regulation (EC) No. 10/2011, Regulation (EC) No. 1935/2004 and Regulation (EC) No. 2023/2006 on Good Manufacturing Practice. Not all types of gloves can be used in contact with all types of food. Some gloves can release harmful substances that pass directly into the food. For detailed information, please contact Medasept S.A. Gloves are suitable for handling any type of food and have been tested for Overall Migration Test acc. EN 1186:

Storage Instructions:

- Protect from sunlight, fluorescent light and ozone
- Store in a dry place at 10-30 ° C
- The recommended relative humidity of the room in which the gloves are stored is 60 ± 20%
- Store gloves at a distance of not less than 1 m from heating devices and fire sources

- Do not store in the immediate vicinity of solvents, oils, fuels, greases
- Cartons of gloves are suitable for transport and storage

Precautions and indications for use:

- Before use, check the gloves for defects
- Disposable gloves - use a minimum of 1 pair of gloves for one patient and one medical procedure
- During use, gloves should be immediately replaced with new ones if they are cracked, torn or pierced
- When using the gloves, use mild washing and disinfecting agents that do not irritate the skin of the hands
- Before putting on gloves, it is recommended to dry the skin thoroughly
- It is recommended that you wash your hands thoroughly, dry them and apply a care cream after taking off the gloves
- Keep all chemicals away from the skin, even if they are not hazardous
- If the chemical substance gets into the skin, it should be washed off immediately with plenty of water and soap
- Avoid using gloves that are dirty on the inside - they may cause irritation leading to dermatitis or more serious injuries
- Do not use gloves where there is a risk of being caught by the moving parts of the machines
- The gloves should not be used in contact with open fire and for protection against any sharp tools
- Gloves are not intended for welding, protection against electric shock, ionizing radiation, and against the effects of cold and hot objects
- Do not use after the expiry date
- After use, dispose of the product in accordance with applicable regulations

Components / hazardous components:

Some gloves contain ingredients that are known to cause allergies in allergic individuals who may develop contact irritation and / or an allergic reaction.
In the event of an allergic reaction, seek medical attention immediately.

Final Remarks:

The information contained in this document is intended to assist the user in selecting the appropriate personal protective equipment. The results of research and laboratory tests are intended to facilitate selection, but do not simulate real operating conditions. It is the user's responsibility to make the final decision on whether or not to use the PPE for the intended operation. A partially torn or damaged product should be immediately withdrawn from use, because it does not provide the protection declared by the manufacturer, and its continued use may cause additional hazards. The gloves do not protect against risks not listed in this document

Manufacturer:

Medasept S.A. ul. Forteczna 19, 61-362 Poznań, www.medasept.com

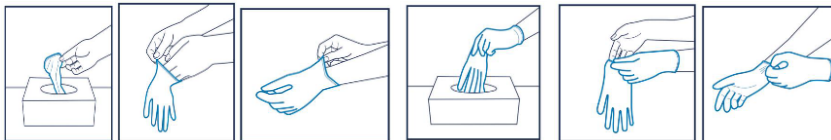
Test results:

EN ISO 374-1:2016 Classification of Permeation Performance Levels	
Permeation Performance Level	Measured Breakthrough time (min)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

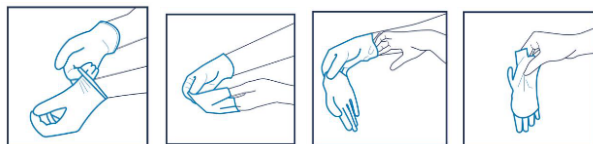
Code Letter	Chemical Permeation EN ISO 374-1:2016	Level	Mean Degradation EN 374-4:2013
K	40% Sodium Hydroxide	6	-25.6%
P	30% Hydrogen Peroxide	2	17.0%
T	37% Formaldehyde	6	3.1%

EN ISO 374-5:2016	Result
Resistance against Bacteria and Fungi	Pass
Resistance against Virus	Pass

INSTRUCTION FOR PUTTING GLOVES


















INSTRUCTION FOR TAKING OFF GLOVES



SYMBOL USE ON THE PACKAGING

	for single use		package made from paper, qualify for recycling
	non- sterile gloves		packaging can be treated as municipal waste

	medical device		the product meets the essential normative requirements
NITRIL	gloves made from nitrile	 www.medasept.com	instrukcja użytkowania do pobrania ze strony www.medasept.com . Do otwarcia wymagany jest darmowy program do pobrania ze strony https://get.adobe.com/pl/rader/
	protect from sunlight and fluorescent light	 Medasept S.A. ul. Forteczna 19 61-362 Poznań POLAND www.medasept.com	manufacturer 's data
	protect from moisture, store in a dry place		the quality of the gloves is not guaranteed if the packaging is damaged
	glove store in temperature 10 - 30°C	 This product is suitable for food handling excluding acidic foodstuffs for 2 hours at 40°C (EU No. 10\2011)	the product is suitable for contact with food
LOT	nr partii nadawany przez wytwórcę		expiry date
	data produkcji	 100 by weight	100 gloves by weight
EN ISO 374-1:2016 / Type B  KPT	type B chemical risk resistant gloves, three chemicals labelled with a letter below the pictogram	 200 by weight	200 gloves by weight
EN ISO 374-5:2016  VIRUS	gloves resistant to bacteria, fungi and viruses		