MEDASEPT S.A.

Instructions for use: Powdered Vinyl Gloves

Brand: medaSEPT vinyl blue

Ref: MSVB100

Basic UDI-DI: 590173887RDVQ4

Product:

Vinyl examination and protective gloves, powdered, non-sterile for disposable use

Description of the product:

Raw material: vinyl
External Surface: smooth
Colour: clear blue
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

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 to 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 I Personal Protective Equipment as per Annex I of the Regulation 2016/425 [PPE] and comply to standards: EN 420:2003+A1:2009

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.

Storage Instructions:

- Protect from sunlight, fluorescent light and ozone
- > Store in a dry place at 5-30 °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, <u>www.medasept.com</u>

INSTRUCTION FOR PUTTING GLOVES













INSTRUCTION FOR TAKING OFF GLOVES









SYMBOL USE ON THE PACKAGING

	1		
2	for single use	PAP	package made from paper, qualify for recycling
NON	non- sterile gloves		packaging can be treated as municipal waste
MD	medical device	C€	the product meets the essential normative requirements
VINYL	gloves made from vinyl	www.medasept.com	instructions for use available for download at www.medasept.com, to open, you need a free download from https://get.adobe.com/pl/rader/
类	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	100 by weight	100 gloves by weight
5°C 5°C	glove store in temperature 5 - 30°C		the quality of the gloves is not guaranteed if the packaging is damaged
LOT	lot/ batch number given by the manufacturer	7 %	the product is suitable for contact with food
س	date of Manufacturer		expiry date