

Examination Gloves (Diagnostic) APEXMED Clemas, Vinyl, Nonsterile, Powder Free

Operating Manual

Apexmed International bv
Keizersgracht 62-64
1015 CS Amsterdam
The Netherlands

t +31 (0)20 520 7560
f +31 (0)20 520 7510
e info@apexmed.nl
w www.apexmed.eu

Bank ING
IBAN € NL96INGB0674235010
IBAN \$ NL34INGB0020286279
BIC INGBNL2A

KvK 34159173 Amsterdam
BTW 810618114-B01

1. Intended Use.

Examination gloves (diagnostic) APEXMED vinyl, nonsterile, powder free are intended to protect patients and medical personnel from cross-contamination during various procedures. The device serves as protection barrier wearing on personnel hands during patient's examination/treatment or for other sanitary purposes. The device protects medical personnel and patients hands from contaminations. The gloves are resistant to blood impact, semen or cervical secretions, other biological liquids and chemical agents.

2. Indications for gloves applications.

- possible contact with blood;
- contact with semen or cervical secretions;
- contact with the mucous membranes of the nose, mouth, genitals, rectum;
- contact with a biological fluid, regardless of the blood presence;
- contact with objects or materials contaminated with blood or other body fluids;
- any violation of the integrity of the skin of the patient or medical personnel;
- possible contact with the patient's bedding;
- laboratory tests.

3. Contraindications to the use of gloves

Allergic skin reactions such as contact dermatitis may be caused by the components used in the production of vinyl gloves.

In the case of allergic reactions / contact dermatitis product, immediately discontinue use and consult a doctor.

4. Safety Measures.

- All manipulations connected with risk of hands contamination with blood or serum or chemical agents, must be performed with gloves;
- All injuries on hands must be covered with plaster, watertight dressing;
- In case of skin contamination with blood it must be cleaned as soon as possible considering patient's safety:
- take off the gloves;
- treat the skin with pad, wet with 70% alcohol;
- wash the skin with soap and dry with swab;
- repeat treatment with 70% alcohol.

5. Working Principle.

Examination gloves (diagnostic) APEXMED vinyl, nonsterile, powder free are intended to protect patients and medical personnel from cross-contamination during various procedures.

The device serves as protection barrier, impervious for biological agents, wearing on personnel hands during patient’s examination/treatment or for other sanitary purposes. The device protects medical personnel and patients hands from contaminations. The gloves are resistant to blood impact, semen or cervical secretions, other biological liquids and chemical agents.

6. Main Characteristics.

Examination (diagnostic) gloves APEXMED Clemas, vinyl, non-sterile, powder free, smooth, ambidextrous (for both hands), color: white, sizes: XS, S, M, L, XL.



Size table

Medical device name	Size	Width, mm	Length, min (mm)	Thickness, min (mm)
Examination (diagnostic) gloves APEXMED Clemas, vinyl, non-sterile, powder free, smooth, ambidextrous (for both hands), color: white, sizes: XS, S, M, L, XL	XS	76 ± 3	240	Fingers: 0.12±0,02
	S	84 ± 3		Palm: 0.10±0,02
	M	94 ± 3		Cuff: 0.10±0,02
	L	105 ± 3		
	XL	113 ± 3		
Thickness of the Corolla glove (mm)	0,12±0,09			
The weight of one glove (g)	4-5,5			

Materials applied for production of examination (diagnostic) gloves APEXMED vinyl, nonsterile, powder free:

- The components of the gloves:
- polyvinyl chloride (PVC) - colorless, transparent plastic, a thermoplastic polymer of vinyl chloride. Different chemical resistance to alkalis, mineral oils, many acids and solvents. Off the air and has a low resistance to frost;
 - atsetiltributitsitrat (ATVS) - colorless transparent Jew-bone. Secure plasti-cizer mainly used for PVC, cellulose resins and synthetic rubber. It is also used as a stabilizer of PVC;

- calcium-zinc stabilizer - a complex inorganic substance used as a stabilizer in the PVC manufacturing;
- paraffin oil - a high boiling petroleum distillate, mineral wax and resins of various origin containing more or fewer paraffin. It is used for the preparation of lubricants or, after a preliminary chemical purification of sulfuric acid and alkali;
- polyurethane - hetero-polymer. It refers to the synthetic-sky elastomers, widely used in industry for a wide range of strength characteristics. It used as substitutes for the manufacture of rubber products, in aggressive environments in conditions of high alternating loads and temperatures;
- PW6 (6Titanium dioxide (Pigment White)) - inorganic co-unity, fine, white powder. Used in the production-stve rubber and rubber goods rubber matting.

Strength and airtightness requirements

No.	Medical device name	Strength testing results	Airtightness testing results
1	Examination (diagnostic) gloves APEXMED Clemas, vinyl, non-sterile, powder free, smooth, ambidextrous (for both hands), color: white, sizes: XS, S, M, L, XL	Before enhanced ageing: force at break: min 9 H, elongation at break: min 450%, After enhanced ageing: force at break: min 7 H, elongation at break: min 400%	when gloves are filled with 1000 ml water there is no leakage.

7. Work order with medical examination (diagnostic) gloves

1. Treat hands.
2. Open the box, take a pair of gloves and unfold the pack.
3. Take glove for right hand by flap preventing touching of inside glove surface.
4. Close fingers of the right hand and insert them into the glove.
5. Put on the gloves not disturbing its flap opening fingers of the right hand.
6. Take the left glove with 2nd, 3rd and 4th fingers of the right hand (in glove) by the flap preventing touching of inside glove surface.
7. Close fingers of the left hand and insert them into the glove.
8. Smooth flaps on the left and then on the right hand pulling them on the sleeves.

Steps of taking off the gloves

1. To make a cuff on the left glove by the fingers of the right hand, touching only the outside (preventing contamination of the forearm

skin or sleeves of the gown if gloves cover the lower part of the sleeves).

2. Take off the glove from the left hand, inverting it inside out and holding the cuff. Keep it in the right hand (preventing contamination of the environment).
3. To take the left glove by the left hand by the cuff on the inside (preventing contamination of the left hand).
4. Take off the glove from the right hand, inverting it inside out so the left glove appeared in the middle of the right (preventing contamination of the environment, providing infectious safety)
5. To put the gloves in the disinfectant solution (preventing distribution of microorganisms in the environment)
6. Perform hand hygiene treatment.

8. Disinfection and Disposal.

According to the current regulations, disposable gloves are subject to disinfection and disposal after use.

Immediately after use medical gloves are took off and immersed in disinfectant solution directly in the place of use. For this purpose the following solutions are used: 6% hydrogen peroxide, 3% solution of bleach, 1.5% sodium hypochlorite, calcium 2% solution lizoformita 3000. Exposure to these disinfectants is 60 minutes.

After disinfection disposable gloves must be disposed.

Examination gloves (diagnostic) vinyl, nonsterile, powder free are biohazard waste. Treatment and utilization according to the set rules must be performed.

Gloves utilization is performed by means of packs, bags and containers similar to utilization of dressing materials, after preliminary disinfection.

It is permitted to burn vinyl gloves. Vinyl gloves can be disposed this way without any harm to environment or human health.

The class of hazard medical wastes based on the characteristics of morphological composition of class B (epidemiologically hazardous waste).

Operation environment.

Operating Conditions

- For single use
- The temperature from + 35 °C to 10 °C
- Relative humidity: from 60% to 80%
- Atmospheric pressure 700gPa to 1060gPa
- Protect from moisture and direct sunlight

Storage

- The temperature from +5 to +30 ° C

- Relative humidity: from 60% to 80%
- Atmospheric pressure 700gPa to 1060gPa
- Protect from moisture, direct sunlight and ionizing radiation
- Storage to use in packaging
- Storage 5 years

Warranty

The manufacturer guarantees the safety of all the properties viewing gloves (diagnostic) APEXMED latex, non-sterile, powdered for 5 years from the date of production, if the integrity of the packaging and storage conditions are observed

Transport conditions

Glove boxes are transported in vehicles covered by any type of transport in accordance with the applicable rules and regulations of cargo transportation by this type of transport, at a temperature of -10 to + 40 ° C

9. Handling.

Transportation of the packed gloves should be carried out by all kinds of transport in covered vehicles in accordance with the rules of transportation of goods, applicable to each type of transport. Transportation by rail is carried out by the container shipments.

10. Manufacturer:

«Apexmed International B.V.»

Keizersgracht, 62-64, 1015 CS Amsterdam, the Netherlands

www.apexmed.nl, www.sensitec.nl

Production Sites: Apexmed International B. V., Keizersgracht, 62-64, 1015 CS Amsterdam, the Netherlands.

TG Medical Sdn. Bhd., Lot 5091 Jalan Teratai, Batu 5, off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia

11. Organization, authorized by the manufacturer on the acceptance and satisfaction of the requirements from consumers regarding products of inadequate quality: "Medicom Co., Ltd.", Russian Federation, 143570 Moscow region, Novopetrovskoe settlement, Pervomayskaya str., 59, Tel./Fax: +7 (495) 651-91-16, email: medicom@inbox.ru

Managing Director

«Apexmed International B.V.»

Signature

15.03.2016



Rashid R. Biktogirov

Name

Apexmed International B.V.

Keizersgracht, 62-64, 1015 CS,

Amsterdam, the Netherlands

Managing Director

Rashid R. Biktogorov

