User Manual of Polyisoprene Surgical Gloves

Manufacturer (name and address):	Guilin HBM Health Protections, Inc. No. 1-2, Shuijing East Road, Economic and technological Development Area, Guilin, 541805, China Tel: 86-773-2550119 Email: export@hbmchina.com
EC Representative (name and address):	HBM Medical Coliemore House, Coliemore Road, Dalky, Co. Dublin, A96 A8D5, Ireland Tel: 0044 7709045852 Email: maurice@4shbm.com

1. Device Identification:

Proprietary Name:	Medispo Polyisoprene Surgical Gloves
Common Name:	Single-use sterile polyisoprene surgical gloves
Device Class	IIa as per EU MDR 2017/745
Rule	Rule 6 as per EU MDR 2017/745

2. Indication for Use:

The PI Surgical Gloves is a disposable device that is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious material and other contamination

The gloves are appropriate for use during invasive and non-invasive medical procedures requiring sterility. They are designed to be worn by operating room personnel. The PI Surgical Gloves are designed for use in the environments within hospitals and other healthcare facilities.

3. Device Description:

The Medispo Polyisoprene Surgical Gloves are made of polyisoprene rubber latex, based on the technology of "latex dipping", similar to that for making latex condoms. The gloves are anatomical in structure, either smooth- or texture-surfaced, with or without a rolled rim at the cuff. They come in nine sizes (5.5",6", 6.5", 7", 7.5", 8", 8.5", 9",9.5") to suit different users, all sharing the same color, creamy white.

The gloves are powder-free, meaning that no powder is incorporated for purposes other than manufacturing, from which only residual powder is left with the final finished product. To attain easy donning, the technique of "polymer coating" is employed to coat the gloves' inside surface with a thin, smooth layer of polymer, polyurethane.

The gloves are radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6} and are packaged in

sterility maintenance packages to ensure a shelf life of 3 years.They are limited to single use only, and repeated use or repeated sterilization is not allowed in surgical application.

4. Specifications

4.1 Dimensions (Length & width & single wall thickness, mm)

The dimensions of the gloves comply with the requirement in the following table:

Size	*Length*	*Width*	*Thickness*
5.5	250mm min	72±4mm	Smooth area: 0.10mm min Textured area: 0.13mm min
6	260mm min	77±5mm	
6.5	260mm min	83±5mm	
7	270mm min	89±5mm	
7.5	270mm min	95±5mm	
8	270mm min	102±6mm	
8.5	280mm min	108±6mm	
9	280mm min	114±6mm	
9.5	280mm min	121±6mm	

The compliance level is an AQL of 4.0.

4.2 Strength

The force at break of the gloves (median of 13 gloves) is not less than 9.0N.

4.3 Watertightness

The gloves are so designed and manufactured that they have adequate watertightness and are free from holes to function as a barrier against microorganism transmission. The compliance level is an AQL of 0.65.

4.4 Residue powder content： ≤ 2.0mg/glove

4.5 Sterility

The gloves are provided pre-sterilized, using ionizing radiation to acheive a SAL of 10^{-6}.

The periodc documented validation of the effectiveness of the sterilization method and audit of the appropriateness of the established radiation dose is conducted in accordance with ISO 11137-1 and -2 to ensure the sterilization activity is reliable and reproducible.

5. Types

Where their finish is concerned, the gloves are divided into two types, smooth and textured. The former is smooth all over, whereas the latter has a textured area covering the palm and the front part of the thumb and fingers.

In terms of how the cuff is formed, the gloves also have two types, cuffed and uncuffed. A cuffed glove has a rolled rim at the cuff, and an uncuffed one does not.

6. Packaging:

The gloves, with their wrists turned inside out, are placed in pairs into paper wrappers, which are then packaged in paper or poly pouches. After being sealed by the sealing machine, the pouches are put into boxes, which are then packed into outer cartons prior to sterilization.

The effectiveness of the sealing process is periodically validated in accordance to ISO 11607-2 to ensure that sterile barrier system integrity is attained in a reliable and reproducible manner.

7. Shelf life:

The Medispo Polyisoprene Surgical Gloves have a claimed shelf life of 3 years at 25℃ based on the accelerated aging study data.

8. Biocompatibility

The Medispo Polyisoprene Surgical Gloves have undergone various relevant biological tests, including skin irritation test, sensitization test, *in vitro* cytotoxicity test, material mediated pyrogenicity test, acute systemic toxicity test, and heamolysis test, in accordance with ISO 10993 series. The data generated from the tests collectively support the conclusion that the gloves have good biocompatibility and are safe to both users and patients when used according to their intended application.

9. Instruction for use:

- Please use before the expiry date as indicated by package labeling.
- Select the right size that best suits your hands.
- For easy donning, dry your hands if they are wet.
- Avoid any sharp or barbed objects to prevent puncture or cut in the gloves. Trim your fingernails if necessary.
- If the gloves are found broken during use, discard them and use a new pair after hand disinfection.
- Replace the gloves with a new pair if they have been in use for more than 4 hours to prevent the risk of glove damage from increasing.
- Do not expose this product to intense light, such as sunlight or ultraviolet ray.
- Avoid contact with oils, acids, alkalis, or other chemicals that can have damaging effects on rubber.

10. Warning:

- Do NOT use if the sterile package is damaged or unintentionally opened before use.
- This product is disposable and for single use only. Reuse of this product may increase the risk of contamination.
- Dispose of this product as medical waste after use, since the used gloves may be contaminated with potentially infectious substance of human origin.

11. Storage conditions:

Store in a cool, dry, and well-ventilated environment free of any corrosive gases. Shield open boxes from direct sun and fluorescent lighting.

12. Notice:

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.