

YAAN-DEVICE CO., LTD

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Yaan's copolymer gloves has been sold worldwide around 30 years, we are qualified by ISO 13485 and CE 2460. Due to the gloves on paper technology, the seam strength is better than the similar type of products like PE gloves without paper. Yaan's glove is sterilized by Gamma Ray, fully adequate for many nursing activities and examinations, ex: dialysis, intubation, Gynaecology clinics. Due to the outstanding physical property and easy donning, medical staffs can wear Yaan's copolymer gloves to do a quickly examination without take out their latex gloves or vinyl gloves in the emergency room or isolate units. It can reduce the use of latex or vinyl gloves and also reduce the cost, especially for the purpose to use the sterile items. The copolymer gloves are powder free, DOP free and contains no latex protein. It is valued because latex protein cause a large majority of people to suffer from skin allergies and will provoke the onset of asthma and heart diseases in a proportion of users. The copolymer gloves can be wore under latex gloves to prevent allergy problem.

DISPOSABLE COPOLYMER EXAMINATION GLOVES



ITEM NO. YN-66-SPS
GLOVES ON PAPER, STERILE
PACKING: 1PC/BAG, 100BAGS/BOX
2,400BAGS/CTN



ITEM NO. YN-66-DPS
GLOVES ON PAPER, STERILE
PACKING: 2PCS/BAG, 50BAGS/BOX
1,200BAGS/CTN



ITEM NO. YN-66-PS
GLOVES ON PAPER, STERILE
PACKING: 100PCS/POLYBAG THEN
PUT IN TO BOX
2,000PCS/CTN



ITEM NO. YN-66-P
GLOVES ON PAPER, NON-STERILE
PACKING: 100PCS/BOX
2,000PCS/CTN

Labels (IFU)

1. Description of Products/ Intended for Use

Product : **Copolymer Examination Gloves**
Product Mode : **YN-66-SPS (Single Packed, sterile)**
YN-66-DPS (Pair/ Double Packed, Sterile)

COPOLYMER EXAMINATION GLOVES

NON POWDER

FIT EITHER HAND,

NON-ALLERGIC

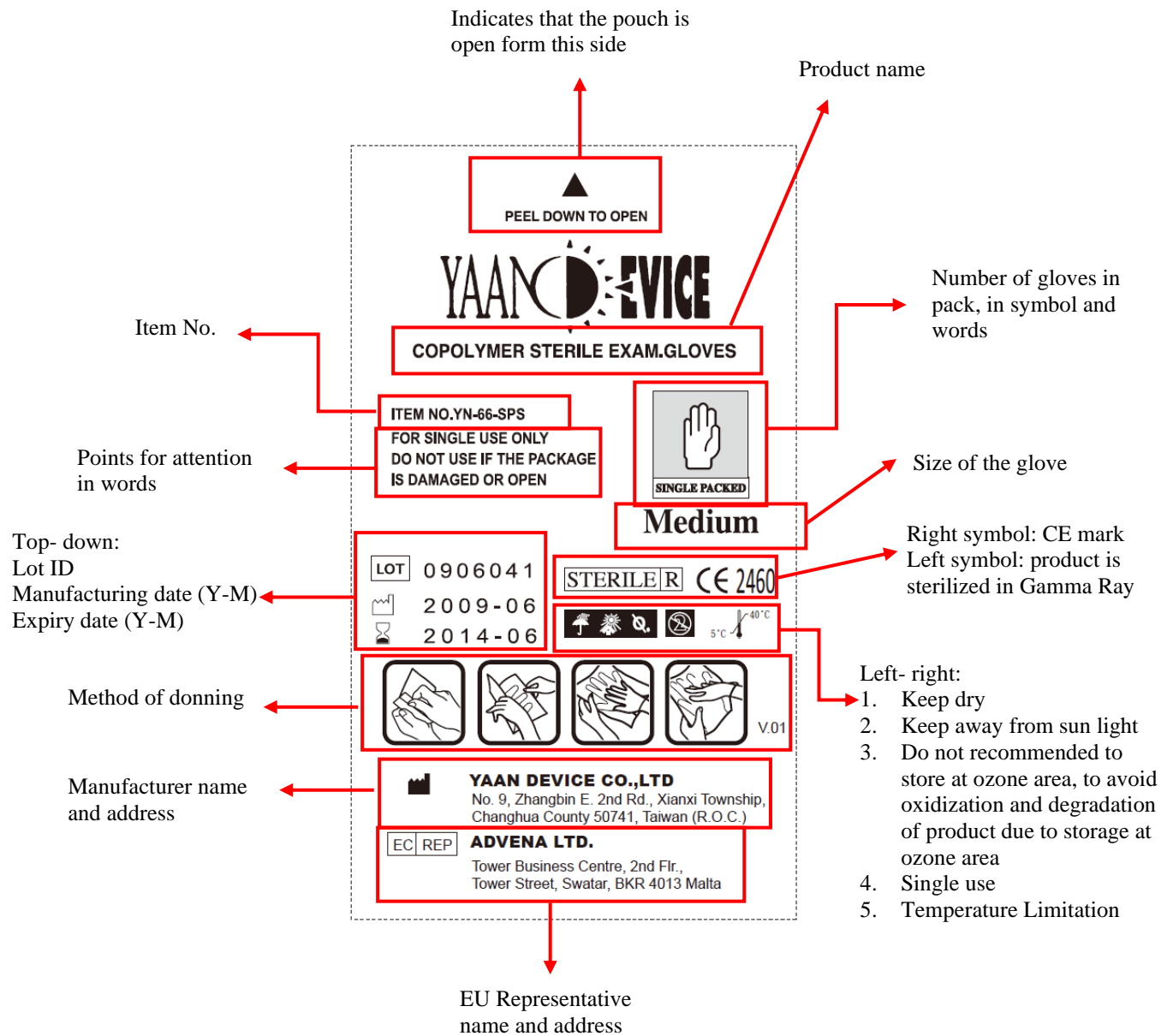
The glove is manufactured from EVA offers high level of the flexibility, comfort and sensitivity. Copolymer Examination glove is bonded on a paper and is fully adequate for many nursing activities and examinations as well as protects both wearer and patient against allergic reaction and contamination.

Most of the gynecologist uses the Copolymer sterile Exam. Glove in gynecology. The glove is also adequate by doctor for wound care or to be used in intensive care unit.

Some of the doctor who has an allergy to latex protein use Copolymer Examination glove as the first layer glove before they put on latex surgical gloves. The risks caused by latex are avoided.

The device is intended for the covering of medical staff's hand during examination or nursing procedure on patient's skin.

2. Description of the Symbols on the Unit Product



3. Open of the Unit Product

3.1 Drawing (Description of Donning)

Version V.01



1. peel down the paper bag to open



2. Take the paper out and make it flat

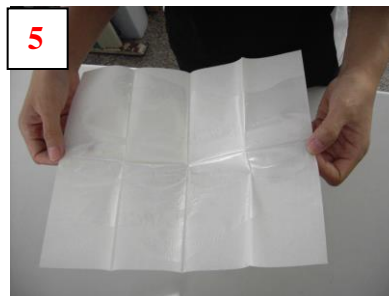
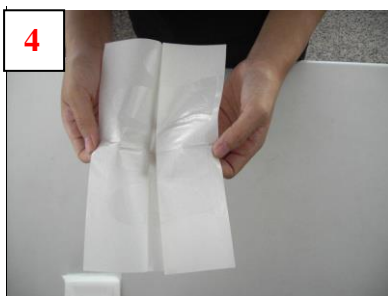
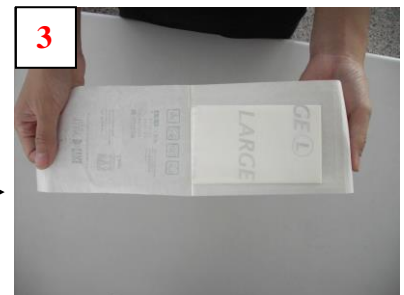
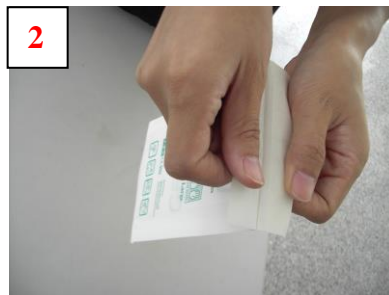


3. Put the hand into glove



4. Peel the glove from paper

3.2 Display



4. Residual risks/ Warnings:

- a. Single use only, reuse may cause contaminations and infections.
- b. Do not use if the Package is damaged or opened, it may cause contaminations and infections.
- c. Keep dry, keep away from sun light
- d. Disposal: Disposal should consult local laws and regulations. Both gloves and packages are made in non-toxic materials, could be disposed in a general waste bin. Safe burning through a waste incinerator is preferred.
- e. Indication: Use when the user needs to protect their hands from contact infection
- f. Contraindication: When the user is allergic to the glove material (EVA copolymer)
- g. Side effect: May cause allergic reaction in user

Special note: A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established

5. Identification of manufacturer

Manufacturer: YAAN DEVICE CO., LTD.
No. 9, Zhangbin E. 2nd Rd., Xianxi Township,
Changhua County 50741, Taiwan (R.O.C.)
Tel: 886 4 758-4048 Fax: 886 4 758-5600

Strilization Center: China Biotech Corporation
10,33rd Road, Taichung Industrial Park,
Taichung, Taiwan
Tel: 886 4 359-7515 Fax: 886 4 359-7080

Authorized Representative:

ADVENA LTD.
Tower Business Centre, 2nd Fl.,
Tower Street, Swatar, BKR 4013 Malta
Tel: +356 2546 6689

Notify Body: DNV Product Assurance AS (2460)


6. Sample of label (paper pouch)

▲
PEEL DOWN TO OPEN

YAAN DEVICE





COPOLYMER STERILE EXAM.GLOVES





ITEM NO.YN-66-SPS
 FOR SINGLE USE ONLY
 DO NOT USE IF THE PACKAGE
 IS DAMAGED OR OPEN


 SINGLE PACKED


Medium


LOT 0906041 STERILE R CE 2460

 2009-06
  2014-06
 
 5°C  40°C

V.01

 **YAAN DEVICE CO.,LTD**
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 Changhua County 50741, Taiwan (R.O.C.)


 **ADVENA LTD.**
 Tower Business Centre, 2nd Flr.,
 Tower Street, Swatar, BKR 4013 Malta

▲
PEEL DOWN TO OPEN

YAAN DEVICE





COPOLYMER STERILE EXAM.GLOVES





ITEM NO.YN-66-DPS
 FOR SINGLE USE ONLY
 DO NOT USE IF THE PACKAGE
 IS DAMAGED OR OPEN


 PAIR PACKED


Medium


LOT 0906041 STERILE R CE 2460

 2009-06
  2014-06
 
 5°C  40°C

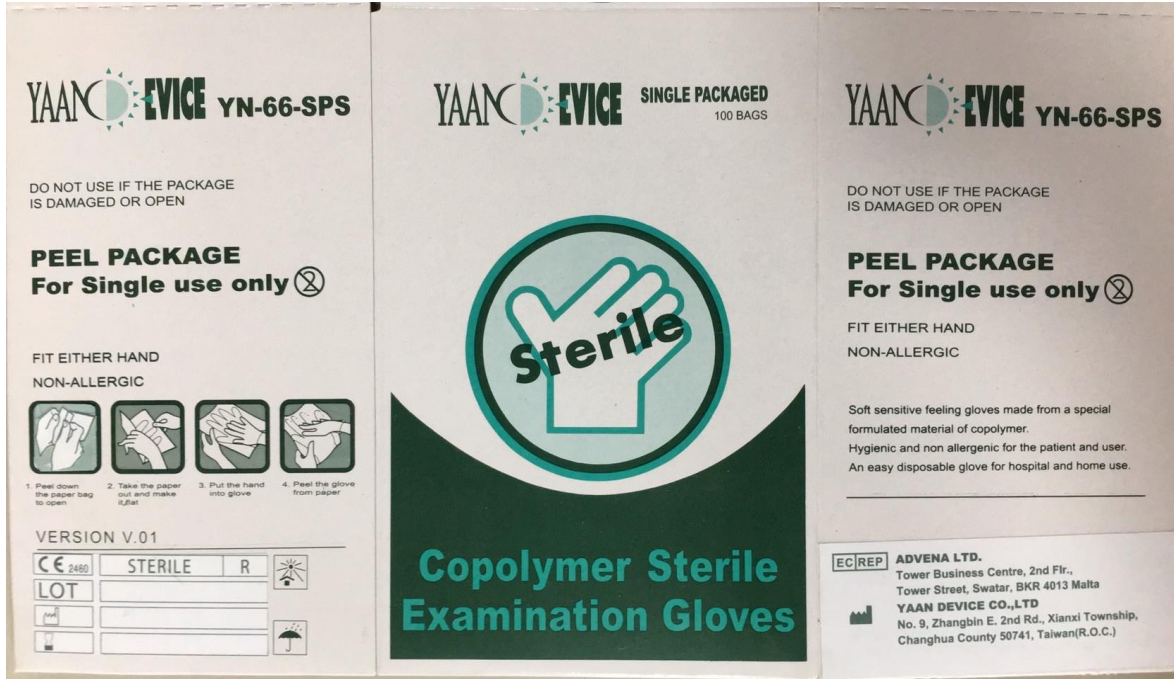
V.01

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7. Sample of label (inner box of Item No. YN-66-SPS)

Single Packed
Item No. YN-66-SPS



Pair Packed
Item No. YN-66-DPS



8. Version History

Version	Compiled by	Date	Description
1	Juliee Hsieh	2019/08/20	First issue.
2	Juliee Hsieh	2020/08/20	Add temperature limitation
3	Juliee Hsieh	2022/01/10	Revise 4. Residual risks/ Warnings