

Medical Device Product Technical Requirements No:

Disposable Isolation Gown

1. Product model / specification and its division description

1. 1 Product name: disposable isolation gown

1. 2 Product models are divided into: Sewing type conjoined、 Sewing split type、 Sewing reverse wear type、 Thermal conjoined type、 Thermal split type、 Thermal reverse wear type.

1. 3 Product specifications are divided into: S (small), M (medium), L (large), XL (plus), XXL (plus), XXXL (three plus).

1. 4 According to the medical device management classification, it belongs to Class I 14-14-03, non-sterile, single use.

1. 5 Basic structure of disposable medical isolation gown: It is made of nonwoven cloth material, the cuff is elastic, the back is fully opened by tight cloth belt, and the cloth belt is heated or sewn with non-woven cloth. Split type for the jacket with pants, the jacket can be long sleeve closed or short sleeve mouth structure. The conjoined type is zipper structure for the upper body.

1.6 Product classification

The non-woven fabric for medical disposable isolation gown is classified as grade I, gradeII, grade III and gradeIV according to its internal quality requirements, and its protective performance is improved step by step.

Note: Grade I-generally used for visitation, cleaning, etc.

Grade II—Generally used for routine care and examination.

Grade III—Generally people wear in a certain amount of bleeding, fluid secretions occasions

Grade IV—Generally people wear when clean medical waste or face large amounts of patients' blood and body fluid for a long time.

2、 Performance index

2.1 Dimensional requirement

It shall meet the requirements of Table 1.

Table 1

Unit : cm

| Model Size | | Sewing reverse wear type, Thermal reverse wear type | | | | | |
|------------------|------------------|---|---------------------------|---------------------------|---------------------------|---------------------------|---------------------|
| | | S (small) | M (medium) | L (large) | XL (large plus) | XXL(large 2 plus) | XXXL(large 3 plus) |
| length×width | | 110 ~ 119×110 ~120 | 120 ~ 130×120 ~ 130 | 120 ~ 130×131 ~ 144 | 120 ~ 130×145 ~ 149 | 120 ~ 130×150 ~ 159 | 120~ 140×160~170 |
| shoulder breadth | | 55 | 55 | 56 | 56 | 57 | 58 |
| outside sleeve | | 54 | 56 | 56 | 58 | 58 | 60 |
| deviation | | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm |
| Model Size | | Sewing split type, Thermal split type | | | | | |
| | | S (small) | M (medium) | L (large) | XL (large plus) | XXL(large 2 plus) | XXXL(large 3 plus) |
| j | length×width | 70~79×11 | 80~89×120 ~ | 85~95×120~ | 90~100×120 | 95~105×12 | 105~110×120 |
| | h | 0~119 | 129 | 130 | ~130 | 0~130 | ~140 |
| a | shoulder breadth | 55 | 55 | 56 | 56 | 57 | 58 |
| | outside sleeve | 50 | 50 | 55 | 55 | 60 | 60 |
| t | length×width | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm |
| | h | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm |
| p | length×width | 110×15 | 115×150 | 120×150 | 120×155 | 125×155 | 125×160 |
| | h | 0 | | | | | |
| a | deviation | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm | ±3cm |

| | | | | | | | |
|------------------|--|------------|-----------|------------------|-------------------|--------------------|------|
| n | | | | | | | |
| ts | | | | | | | |
| Model | Sewing type conjoined、Thermal type conjoined | | | | | | |
| Size | S (small) | M (medium) | L (large) | XL (large plus) | XXL(large 2 plus) | XXXL(large 3 plus) | |
| length×width | 165×120 | 169×125 | 173×130 | 178×135 | 181×140 | 187× 145 | |
| shoulder breadth | 58 | 60 | 62 | 64 | 66 | 68 | |
| outside sleeve | 84 | 86 | 90 | 93 | 96 | 99 | |
| deviation | ±5cm | ±5cm | ±5cm | ±5cm | ±5cm | ±5cm | ±5cm |

2.2 Appearance Requirements

2.2.1 The cloth surface of the isolation clothing is uniform and smooth, without micro-holes and crystal points, no obvious creases, broken edges, holes, oil stains, and neatly packed.

2.2.2 The hot closing or sewing mouth is uniform and straight, and the sewing shall not be less than 2 stitches per centimeter.

2.2.3 No raw edges, leaky seams, cracking and other phenomena are allowed in the hot closing or sewing place.

2.3 Structural Requirements

2.3.1 The structure of the isolation clothing should be reasonable, easy to put on and take off, and the structure of the binding part should be consistent.

2.3.2 Cuff adopts elastic closing and tight combination.

2.4 Material characterization requirements

The requirements for physical properties of non-woven materials are shown in Table 2

Table 2

| Product classification | Grade I | Grade II | Grade III | Grade IV |
|--------------------------------------|---------|----------|-----------|----------|
| Square meter mass deviation rate (%) | ±6 | | | |
| Breaking strength(N) | ≥20 | ≥20 | ≥30 | ≥45 |

| | | | | |
|---|-------------|--------------------------------|--------------------------------|---------------------------------|
| Spray impact water seepage (g) | ≤4.5 | ≤1.0 | ≤1.0 | Not require |
| Hydrostatic pressure (kPa) | Not require | ≥1.8 (18cmH ₂ O) | ≥4.4 (45cmH ₂ O) | ≥9.8 (100cmH ₂ O) |
| Microbial penetration resistance | Not require | Not require | Not require | Pass ^a |
| Resistance to synthetic blood penetration grade | Not require | Not require | Not require | ≥4 |
| Bursting strength (kPa) | ≥40 | | | |
| Moisture permeability g/(m ² · 24h) | ≥3600 | | | |
| Antistatic property (surface resistivity) Ω | Not require | ≤1X10 ¹² | | |
| Whether the results of microbial penetration resistance are qualified shall be judged according to YY/T 0689-2008.。 | | | | |

2.5 Microorganisms

The microbiological indicators of the product shall comply with the provisions of Table 3

Table 3

| Project | requirement |
|--|----------------|
| Total number of bacterial colonies CFU/g | ≤150 |
| Total number of fungal colonies CFU/g | ≤80 |
| Coliform bacteria | non-detectable |
| Bacillus pseudomonas aeruginosa | non-detectable |
| Staphylococcus aureus | non-detectable |
| Streptococcus hemolyticus | non-detectable |

3.5 Microorganisms

Test method: The determination of microorganisms shall be tested in accordance with the provisions of Appendix B of GB 15979-2002 and shall comply with the provisions of Table 3.