

Technical requirement number of the medical device product:

Disposable Dental Kit

1. Product model / specification and its division description

1.1 Product model: inspection type, nursing type

1.2 Classification by medical device management: classification code is 17-04, management category class II.

1.3 Sterile supply by supply status

1.4 See the table below for the configuration requirements

Table 1 Note: Special configuration is arranged according to the order contract but is limited to the following table

S/N	Product name	Specifications and models	Quantity	Memo	
1	Facial tissue	15×20cm	1-5 pcs	/	Self-produced parts
2	Medical gauze block	6×8×8 layers or similar specifications	1-5 pcs	/	Self-produced parts
3	Alcohol + cotton ball	Cotton ball ≥0.2g/grain, 75% medicinal alcohol	1-3 bag	/	Self-produced parts
4	Iodine volt + cotton ball	Cotton ball ≥0.2g/grain, 0.5% Effective iodine	1-3 bag	/	Self-produced parts
5	Tray	10X13cm	1-3 pcs	None	bought-in components
6	Plastic tweezer	11.5cm	1-3 pcs	Have a medical device registration certificate	bought-in components
7	Sterilizing forceps	13cm	1-2 pcs	Have a medical device registration certificate	bought-in components
8	Medical skim cotton ball	≥0.2g/grain	2-20 grains	Have a medical device registration certificate	bought-in components
9	Suction pipe		1-2 pcs	None	bought-in components
10	Dental bib	40X50cm	1-2 pcs	None	bought-in components
11	Mouth mirror		1 pc	Have a medical device registration certificate	bought-in components
12	probe		1 pc	Have a medical	bought-in

				device registration certificate	components
13	Tongue depressor		1-2 pcs	Have a medical device registration certificate	bought-in components

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2.1 Configuration, and appearance requirements

Basic configuration of the nursing type including:tray, plastic tweezers, medical gauze block and auxiliary configuration paper towels, medical skimmed cotton ball, absorbent pipe and disposable tongue pressing plate; the examination type consists of basic configuration tray, plastic tweezers and purse. All accessories in the bag shall be free of mirror, probe, iodine volt cotton balls and auxiliary disinfection pliers, alcohol cotton balls, contaminated, undamaged, odorless and tasteless. Plastic accessories should be smooth, uniform color, should not have burrs, flying edge and cracks.

2.2 Medical gauze block

a) The sinking time does not exceed 10s.

b) The quality per square meter shall not be less than 39g.

2.3 Dental scarf

It shall comply with the impermeability water resistance requirements of YY / T 0506.2 standard.

2.4 Alcohol + cotton ball

Should comply with the provisions of Table 1. Alcohol should be able to provide the disinfectant hygiene license, indicate the concentration, meet the "Disinfection Technical Specification" (2017) edition: positive control group should have more bacterial growth, negative control group should be sterile growth, with the average killing value of natural bacteria on the skin surface of 30 batches of 1.00, can be judged as disinfection qualified.

2.5 Iodine + cotton balls shall comply with the provisions of Table 1. Iodophor should be able to provide the disinfectant hygiene license, indicate the concentration, meet the "Disinfection Technical Specification" (2017) edition: the positive control group should have more bacterial growth, the negative control group should be sterile growth, with the average killing value of natural bacteria on the skin surface of 30 batches is 1.00, can be judged as disinfection qualified.

2.6 Clamp-holding force of plastic tweezers

The clamp-holding force shall be greater than 0.5N. Its purchase shall be purchased from the qualified medical device units

2.7 The lip and tooth occlusal of disinfection forceps

Should be bite open freely. Its purchase shall be purchased from the qualified medical device units.

2.8 Mouth mirror lens' appearance, probe firmness

The mouth lens has good appearance and no cracks. The connection between the probe head and the handle should withstand 5N force without falling off. Its purchase

shall be purchased from the qualified medical device units.

2.9 Disposable tongue depressor

Should be unburr and smooth surface. Its purchase shall be purchased from the qualified medical device units

2.10 Medical skim cotton ball

a) It should be soft and elastic white fiber, no color spots, stains and foreign bodies, odorless, tasteless

b) The water absorption per gram of the sample should not be less than 23g. Procurement shall be purchased from qualified medical device units.

2.11 Sterile

The dental kit shall be sterile after confirmed sterilization process.

2.12 Ethylene oxide residue amount

The dental kit should be sterilized by ethylene oxide, and the residual amount of ethylene oxide should be less than or equal to 10mg / kg.

3. Empirical method

3.1 Configuration, appearance

Experimental method: Visual inspection and nasal smell should comply with the provisions of Article 2.1.

3.2 Medical gauze block

Experimental method: Conduct the test according to the methods of Article 5.9 and Article 5.8 of YY 0331-2006, and the result shall meet the provisions of Article 2.2.

3.3 Dental scarf

Experimental method: Conduct the test according to the corresponding method of YY / T 0506.2, and the result shall comply with the provisions of Article 2.3.

3.4 Alcohol + cotton ball

Experimental method: According to the corresponding method in Disinfection Technical Specification (2017), the requirements shall meet Article 2.4.

3.5 Iodine volt + cotton ball

Experimental method: according to the corresponding method in the version disinfection Technical Specification (2017) , should comply with the requirements of article 2.5.

3.6 Clamping force of plastic tweezers

Experimental method: hold both sides of the tweezers handle, pick up the weight greater than 0.5N closed, keep closed.

3.7 The Lip and tooth occlusal of disinfection forceps

Experimental method: open the handle for three times, and the result should comply with the provisions of Article 2.7.

3.8 Mouth mirror lens appearance, probe firmness

Experimental method: visual inspection, test with tension ometer, the result shall comply with the provisions of 2.8.

3.9 Disposable tongue depressor

Experimental method: visual, hand feel, the result should comply with the provisions of Article 2.9.

3.10 Medical skim cotton ball

Empirical method:

- a) Feel, visual inspection, nose smell.
- b) Conduct the test according to Article 4.63 in YY / T0330-2015.

All the above results shall comply with Article 2.10.

3.11 Sterile

Experimental method: Conduct the test according to the method specified in Chapter 2 of GB / T 14233.2-2005, and the result shall comply with the provisions of Article 2.11.

3.12 Ethylene oxide residue amount

Experimental method: Conduct the test according to the method specified in GB / T 14233.1-2008, and the result shall comply with the provisions of Article 2.12.