

## DISPOSABLE SAMPLING SWAB MEDICAL DEVICE DOCUMENTATION

### 1. Product Information

- Commercial Name: Disposable Sampling Swab
- Product's generic name: Disposable Sampling Swab
- Brand: Kangdaan
- Model: Disposable Sampling Swab is a family of 10 models with same specifications expect length and part of body usage: the model BQ series (BQ001, BQ002) used for nasal cavity, the model KQ series (KQ001, KQ002, KQ003, KQ004)
- Packaging specification:
  - Single package: 1 pc/bag;
  - Sales Package: 20pcs/bag; 25pcs/bag; 100pcs/box

### 2. Description of Medical Device

The Disposable Sampling Swab is a family of 10 models with same specifications expect length and part of body usage: the model BQ series (BQ001, BQ002) used for nasal cavity, the model KQ series (KQ001, KQ002, KQ003, KQ004) used for oral cavity, the model BY series (BY001, BY002, BY003, BY004) can be used both in nasal and oral cavity. And the Disposable Sampling Swab is intended for transient use. The Disposable Sampling Swab consists of a Connecting rod, a broken rod, and a sampling head. The long handle is easy to hold and suitable for different groups of people. The soft and slender connecting rod can effectively protect the sampled tissue from injury. The sampling head is composed of nylon fluff and viscose, which is harmless to the human body and microorganism and can maximize the collection and release of samples. The Disposable Sampling Swab can form a sample collection system with the collection tube or transport tube.

### 3. Intended Use

The Disposable Sampling Swab is intended use to collect biological samples from nasal cavity and oral cavity of the human body for biological examination

### 4. Method of use

#### For model BQ001, BQ002:

- Open the package and take out the swab.
- Hold the handle and gently insert the swab into the nose.
- Gently rotate the sampling swab for 3-5 turns, and then take it out slowly.
- Put the extracted sample into the sample collection tube, then break off the swab from the breakpoint, dip the head of the swab in the preservation solution.
- Tighten the cap and mark the information on the tube.

## **For model BY001, BY002, BY003, BY004:**

- Open the package and take out the swab.
- Hold the handle and gently insert the swab into the mouth or nose.
- Gently rotate the sampling swab for 3-5 turns, and then take it out slowly.
- Put the extracted sample into the sample collection tube, then break off the swab from the breakpoint, dip the head of the swab in the preservation solution.
- Tighten the cap and mark the information on the tube.

## **For model KQ001, KQ002, KQ003:**

- Open the package and take out the swab.
- Hold the handle and gently insert the swab into the mouth.
- Gently rotate the sampling swab for 3-5 turns, and then take it out slowly.
- Put the extracted sample into the sample collection tube, then break off the swab from the breakpoint, dip the head of the swab in the preservation solution.
- Tighten the cap and mark the information on the tube.

## **For model KQ004:**

- Open the package and take out the swab.
- Hold the handle and gently insert the swab into the mouth.
- Gently rotate the sampling swab for 3-5 turns, and then take it out slowly.
- Put the extracted sample into the sample collection tube, and the head of the swab should be in the preservation solution.
- Tighten the cap and mark the information on the tube.

## **5. Storage**

Storage Environment: Dry storage at room temperature (Recommend temperature is 2°C~25°C)

## **6. Contraindications**

Flocking may have light micro pricks on the skin, and groups who with allergy to flocking should be used after the allergy test with slight rotation of the nasal cavity.

## **7. Warnings**

1. This product is disposable, don't reuse it.
2. Do not use products whose expiry date is expired or whose package is damaged.
3. Please do not eat, smoke or drink 30 minutes before sampling, to avoid affecting the sampling effect.
4. The used products should be treated according to local medical waste regulations, and cannot be disposed of carelessly

## **8. GMDN/UMDN**

Disposable Sampling Swab by Kangdaan has GMDN code 61164 (Oral/upper respiratory tract specimen collection kit) and UMDN 13914 (Specimen Collecting Swabs), under the category PATHOLOGY



**9. Name and address of manufacturer**

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**10. Name and address of Importer**

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**11. Contact name in case of additional information needed**

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