



## Disposable Virus Sampling Kit Clinical evaluation data

### **1. Intended use of the product**

#### 1.1 Product features

Used for sample (virus) collection, transportation and storage, etc.

#### 1.2 Applicable medical stages

This product can be used in diagnosis and screening stage, but also in treatment or recovery detection stage.

#### 1.3 Main user of the product

Used for the collection, transportation and storage of samples (viruses); the main target is preserving, transporting and storing the specimens for patients from medical institutions or medical research center for subsequent and further analysis.

#### 1.4 Operation requirements of the product

The operator of this product should read the product instructions for use carefully and operate in accordance with the information of instructions for use.

### **2. The expected use environment of the product**

The products are expected to be used in hospitals, medical or clinical laboratory and scientific research institutes. The expected usage environment as follows:

Environment temperature: 18 °C -26 °C;

Relative humidity: 45% -65%;

Atmospheric pressure: 101.3Kpa (a standard atmospheric pressure).



**3. Applicable people**

Used for the collection, transportation and storage of samples (viruses); the main target is preserving, transporting and storing the specimens for patients from medical institutions or medical research center for subsequent and further analysis.

**4. Product contraindications**

There are no contraindications for this product



**5. Comparison description of clinical use of similar products in the market.**

<b>Compare Items</b>	<b>Similar products in the market</b>	<b>Products to be filed</b>	<b>Compare Results</b>
<b>Product name</b>	Disposable Virus Sampling Kit	Disposable Virus Sampling Kit	Equivalent
<b>Manufacturer</b>	Xiamen Zhishan Biotechnology Co., Ltd.	Zhuhai Lituo Biotechnology Co., Ltd.	--
<b>Registration certificate / record number</b>	Minxia Machinery Equipment No. 20200035	To be filed	---
<b>Product description</b>	It consists of sampling swabs and virus transport media (for virus lysate and virus nucleic acid preservation). Non-sterile provided.	It consists of a sampling swab and / or a tube containing virus transport media (non-inactivated / inactivated type).	<b>Basically the same</b>
<b>Intended Use</b>	Used for the collection, transportation and storage of samples (viruses).	Used for the collection, transportation and storage of samples (viruses).	The same
<b>Post-market quality</b>	Good	Unlisted	---

After comparing the effects with the similar disposable virus sampling tubes already in the market, the product can be used for collect, transport and store sample (virus).

**6. Description of adverse events of similar products.**

No.