

Miraclean Technology Co., Ltd.	CE Technical File	File No	MRC-CE-DSS-003-02.12	Version	V1.0
	Instruction for Use	Effective Date	2022-10-28	Page	1 / 6



# Instructions for Use Of Disposable Sampling Swab

Model: 95000A, 95000L, 95000M, 95000N, 95000MV, 95000TG

**Revision records:**

Edition	Effective Date	Summary of revision	Approved by	Audited by	Written by
V1.0	2022-10-28	Initial version	Zhai Ying	Cui Liu	Chen Miao

## Instructions for Use

### [Product Name]

Disposable Sampling Swab

### [Product Model]

95000A, 95000L, 95000M, 95000N, 95000MV, 95000TG

### [Packaging Specification]

Model	Single Package	Middle Package	Transport Package
95000L	1 pc/bag	10 pcs/bag, 50 bags/box	500 pcs/box
95000M, 95000N, 95000MV		20 pcs/bag	5000 pcs/box
		25 pcs/bag	5000 pcs/box
		100 pcs/bag, 50 bags/box	5000 pcs/box
		20 pcs/bag	2000 pcs/box
		50 pcs/bag, 40 bags/box	2000 pcs/box
		100 pcs/bag, 20 bags/box	2000 pcs/box

### [Intended Use]

The Disposable Sampling Swab is intended to collect biological samples from cervix of the human body for biological examination.

### [Intended Users]

This device can be used both by professionals and lay users who are adults.

### [Description]

Model	Description
95000L, 95000M, 95000N, 95000MV	The Disposable Sampling Swab consists of a plastic handle, breakpoint and nylon fiber sampling head which is harmless to the human body and microorganisms and can maximize the collection and release of samples. The long handle is easy to hold and suitable for different groups of people. The Disposable Sampling Swab can form a sample collection system with the collection tube or

	transport tube.
95000A, 95000TG	<p>The Disposable Sampling Swab consists of a plastic handle and nylon fiber sampling head which is harmless to the human body and microorganisms and can maximize the collection and release of samples. The long handle is easy to hold and suitable for different groups of people.</p> <p>The Disposable Sampling Swab can form a sample collection system with the collection tube or transport tube.</p>

### [Dimension]

NO.	Model	Tip Width (mm)	Tip Length (mm)	Break length (mm)	Total Length (mm)
1.	95000A	8.5mm	22mm	/	169mm
2.	95000L	7mm	25mm	45mm	190mm
3.	95000M	4.35mm	20.25mm	49mm	170mm
4.	95000N	5.5mm	20mm	81mm	150mm
5.	95000MV	8mm	25mm	28mm	95mm
6.	95000TG	8.5mm	22mm	/	130mm

*Note: There is a certain deviation range for product dimension parameters.*

### [Contraindication]

If any irritation or allergic reaction occurs, please stop use and ask a doctor.

### [Warnings]

- 1) This is a single-use product, don't reuse it.
- 2) Keep away from flames or sparks.
- 3) Keep out of the reach of children.
- 4) Avoid soaking swabs with preservation solution before sampling.
- 5) Avoid repeated freezing-thawing.
- 6) If any damage of package, please do not use it.
- 7) If it is expired, please do not use it.
- 8) If you are allergic to nylon fiber and plastic material, please do not use it.
- 9) The used products should be treated according to local medical waste regulations, and cannot be disposed of carelessly.

### [Instructions for use]

- 1) Peel apart the sterile package.
- 2) \*<sup>1</sup>Remove the protective cap.
- 3) Use a semi-sit-down mode, hold the handle of swab and put the sampling swab into vagina. \*<sup>1</sup>Until the security block slice touches the vaginal orifice, the head of the swab is not spun out.
- 4) Rotate the swab head 5-6 times and put the swab into the vagina to sampling. \*<sup>1</sup>Keep the security block slice touching the vaginal orifice during the rotate process.
- 5) Remove the sampling swab from the vaginal orifice gently and put it into the collection tube. \*<sup>2</sup>Then keep the tube up and down 10-15 times, and store it to complete the sampling.

(\*1: indicates only applicable to 95000TG model.

\*2: indicates only applicable to 95000TG model, and for the 95000L, 95000M, 95000N, 95000MV model, it needs to break it at the break point.)

#### **[Product performance index]**

- 1) Basic dimensions: Basic dimensions of the product shall meet the requirements of the Dimension.
- 2) Appearance: The product should be clean, odorless, tasteless, and the swab should be soft to the touch. There should be no yellow spots, smudges, foreign objects, and the rod should be smooth.
- 3) \* Connection Strength: When the moving speed of the tensile testing machine fixture is 200mm/min, the pulling force of the sampling head and one end of the connecting rod should be no less than 2N.
- 4) Breaking Strength: The test span shall avoid the depression between the sampling head and the connecting rod, and the swab shall be able to withstand 4N static pressure perpendicular to the axial direction for 15s without permanent deformation or fracture.
- 5) Rotational friction: Use a small piece of black paper or cloth on the table, use rotating friction 360 degrees to rub the sampling head for no less than 3 times, and the amount of nylon fiber shedding from the sampling head shall not exceed 2.
- 6) \* Maximum breaking force: The breaking force at the depression of the sampling head end shall not be less than 2N. The maximum breaking force vertically downward at the depression of the connecting rod at the fixed sampling head end (90° vertical downward pressure) is as following:
  - 95000M/95000N Maximum breaking strength 30N
  - 95000L Maximum breaking strength 35N
- 7) Water absorption of sampling head: Fill the purified water in a clean container, place it

on a weighing balance with an accuracy of not less than 0.001g, and record the reading  $m_1$  of the balance. Immerse the sample head completely below the purified water level. After 15 seconds, the sample head is taken out vertically against the inner wall of the container (the sample head cannot be pressed hard). Record the indicated value of the balance  $m_2$ . The difference between  $m_1$  and  $m_2$  is the water absorption of the sample head. The water absorption of the sample head is  $\geq 0.01g$ .

8) Sterility: The product should be sterile after ethylene oxide sterilization.

(Note: \* indicates not applicable to model 95000A, 95000MV, 95000TG.)









### [Period of Validity]










36 months

### [Storage Conditions]

- 1) Be stored at room temperature.
- 2) It is recommended to be stored in a dry, ventilated, non-corrosive gas environment, away from ignition sources and flammable substances.
- 3) The product should be protected from heavy stress, direct sunlight, rain and snow in the transportation process.

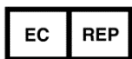
### [Graphs and symbols used for medical device labels]

Symbol	Description of symbol	Symbol	Description of symbol
	Indicates the medical device manufacturer.		Indicates the item is a medical device.
	Indicates the need for the user to consult the instructions for use.		Indicates a medical device that is intended for one single use only.
	Indicates the authorized representative in the European Community.		Indicates the date when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.		Indicates the manufacturer's batch code so that the batch or lot can be identified.

	Indicates the manufacturer's catalogue number so that the medical device can be identified.		Indicates a medical device that has been sterilized using ethylene oxide.
	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.		Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Indicates a medical device that needs to be protected from moisture.		Indicates a medical device that needs protection from light sources.
	Symbol for CE Mark. This symbol certifies that a product has met European Union consumer safety, health, or environmental requirements.		Indicates a carrier that contains unique device identifier information.
	This side up.	/	/

**Miraclean Technology Co., Ltd.**

Room 101 (with production and business premises from 2nd to 5th floor),  
 Building 1, Angeer Factory, No.4, Hetian Road, Shatian Community,  
 Kengzi street, Pingshan District, Shenzhen, Guangdong, P.R. China  
 TEL: 0755-89616773

**Share Info GmbH**

Heerdter Lohweg 83, 40549 Düsseldorf, Germany

**Date of Drafting:** 2022-10-28

**Date of Revision:** V1.0