

Miraclean Technology Co., Ltd.	CE Technical File	File No	MRC-CE-DSS-003-02.2	Version	V1.0
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Instructions for Use

Of

Disposable Sampling Swab

Model: 96000D, 96000E, 96000F, 96000G, 96000DS, 96000GS, 96000GP,
96000M-76, 96000M-100, 96000M-163, 96000N-76, 96000N-103, 96000N-
150, 96000Q

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]

96000D, 96000E, 96000F, 96000G, 96000DS, 96000GS, 96000GP, 96000M-76,
96000M-100, 96000M-163, 96000N-76, 96000N-103, 96000N-150, 96000Q

[Packaging Specification]

Model	Single Package	Middle Package	Transport Package
96000D, 96000E, 96000F, 96000G, 96000DS, 96000GS, 96000GP, 96000M- 76, 96000M-100, 96000M-163, 96000N-76, 96000N- 103, 96000N-150, 96000Q	1 pc/bag	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 nasal 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
96000D, 96000F, 96000G, 96000DS, 96000GS, 96000GP, 96000M-163	The Disposable Sampling Swab consists of a plastic handle, breakpoint and sponge 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.
96000E, 96000M-76, 96000M-100, 96000N-103, 96000N-150, 96000Q, 96000N-76	<p>The Disposable Sampling Swab consists of a plastic handle and sponge 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.	96000D	3mm	14.5mm	78mm	153mm
2.	96000E	3.6mm	11mm	/	68mm
3.	96000F	3.5mm	11mm	22mm	150mm
4.	96000G	4mm	15mm	45mm	75mm
5.	96000DS	3mm	14.5mm	78mm	153mm
6.	96000GS	4mm	15mm	45mm	75mm
7.	96000GP	4mm	15mm	45mm	74mm
8.	96000M-76	6mm	17mm	/	76mm
9.	96000M-100	6mm	17mm	/	100mm
10.	96000M-163	6mm	17mm	55/88mm	163mm
11.	96000N-76	6.5mm	17mm	/	76mm
12.	96000N-103	6.5mm	17mm	/	103mm
13.	96000N-150	6.5mm	17mm	/	150mm
14.	96000Q	6mm	17mm	/	153mm

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 sponge and plastic material, please do not use it.
- 9) Please do not eat, smoke or drink 30 minutes before sampling, to avoid affecting the sampling effect.
- 10) 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) Hold the handle and place the sampling swab into the nose for sampling.
- 3) Rotate the sampling swab gently 3-5 times, and then slowly take out.
- 4) Place the swab into the sample collection tube, break it at the break point (if applicable), and then store it to complete the sampling.

[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) *¹ 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) *² Rotational friction: -Rub the sampling head with a small piece of black paper or cloth on the table for at least 5 times by rotating friction 360 degrees, and detect that the materials of the sampling head will not fall off.
- 6) *¹ 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:

96000D/F/G/GP Maximum breaking strength 2~35N.

96000DS/96000GS/96000M-163 Maximum breaking strength 2~25N.

7) Sampling head firmness: According to the method in T/CSBME 013 (Chinese local standards), thread a 40cm long suture with a needle pass through the top of the sampling head and tie a knot (select the position at the top of the sampling rod that does not directly contact the material of the sampling head to prevent the needle from directly passing through the sampling rod to affect the detection), and hang a 50g weight for 10 seconds. The sampling head shall be firm and not fall off.

8) 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 $\geq 0.01g$.

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

(Note: *¹ indicates not applicable to model 96000E, 96000M-76, 96000M-100, 96000N-76, 96000N-103, 96000N-150, 96000Q.

*² indicates only applicable to model 96000D, 96000F, 96000G, 96000GP.)

[Period of Validity]

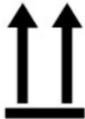
36 months

[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.	/	/

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