

Miraclean Technology Co., Ltd.	CE Technical File	File No	MRC-CE-DSS-003-02.1	Version	V1.0
	Instruction for Use	Effective Date	2022-10-28	Page	1 / 8



Instructions for Use

Of

Disposable Sampling Swab

Model: 93050E-76, 93050E-101, 93050E-152, 93050F-76, 93050F-103, 93050F-150, 93050G-76, 93050G-103, 93050G-150, 93050H-76, 93050H-100, 93050H-163, 93050HZ-163, 93050L, 93050M, 93050T, 93051, 93052, 93053, 93054, 93055, 93050LS, 93050LK, 93050MS, 93050R, 93050S, FS740

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]

93050E-76, 93050E-101, 93050E-152, 93050F-76, 93050F-103, 93050F-150, 93050G-76, 93050G-103, 93050G-150, 93050H-76, 93050H-100, 93050H-163, 93050HZ-163, 93050L, 93050M, 93050T, 93051, 93052, 93053, 93054, 93055, 93050LS, 93050LK, 93050MS, 93050R, 93050S, FS740

[Packaging Specification]

Model	Single Package	Middle Package	Transport Package
93051, 93053	1 pc/bag	30 pcs/case, 20 cases/box	600 pcs/box
93052, 93054, 93055		50 pcs/case, 20 cases/box	1000 pcs/box
93050H-163		50 pcs/bag, 40 bags/box; 20 pcs/bag, 120 bags/box	2000 pcs/box; 2400pcs/box
Other models		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 oral 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
93050E-76, 93050E-101, 93050E-152, 93050HZ-163, 93050L, 93050M, 93050LS, 93050MS, FS740	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.
93050F-76, 93050F-103, 93050F-150, 93050G-76, 93050G-103, 93050G-150, 93050H-76, 93050H-100, 93050H-163, 93050T, 93051, 93052, 93053, 93054, 93055, 93050LK, 93050R, 93050S	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. The Disposable Sampling Swab can form a sample collection system with the collection tube or transport tube.

[Dimension]

NO.	Model	Tip Width (mm)	Tip Length (mm)	Break Length (mm)	Total Length (mm)
1.	93050E-76	8.5mm	25mm	35mm	76mm
2.	93050E-101	8.5mm	25mm	35mm	101mm
3.	93050E-152	8.5mm	25mm	35mm	152mm
4.	93050F-76	6.5mm	25mm	/	76mm
5.	93050F-103	6.5mm	25mm	/	103mm
6.	93050F-150	6.5mm	25mm	/	150mm
7.	93050G-76	8.5mm	25mm	/	76mm
8.	93050G-103	8.5mm	25mm	/	103mm
9.	93050G-150	8.5mm	25mm	/	150mm
10.	93050H-76	6mm	17mm	/	76mm
11.	93050H-100	6mm	17mm	/	100mm

12.	93050H-163	6mm	17mm	/	163mm
13.	93050HZ-163	6mm	17mm	55/88mm	163mm
14.	93050L	4mm	15mm	78mm	153mm
15.	93050M	4mm	15mm	95mm	153mm
16.	93050T	14mm	27mm	/	152mm
17.	93051	12.5mm	21mm	/	84mm
18.	93052	8.5mm	13mm	/	100mm
19.	93053	12.5mm	10mm	/	73mm
20.	93054	14mm	21mm	/	95mm
21.	93055	13.5mm	10mm	/	85mm
22.	93050LS	4mm	15mm	78mm	153mm
23.	93050LK	4mm	15mm	/	153mm
24.	93050MS	4mm	15mm	95mm	153mm
25.	93050R	13mm	24mm	/	129mm
26.	93050S	19.5mm	27mm	/	125mm
27.	FS740	6mm	17mm	55mm	163mm

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) Models other than 93051, 93052, 93053, 93054, 93055 model:

- a) Peel apart the sterile package.
- b) Hold the handle and place the sampling swab into the mouth for sampling.
- c) Rotate the sampling swab gently 3-5 times, and then slowly take out.
- d) Place the swab into the sample collection tube, break it at the break point (if applicable), and then store it to complete the sampling.

2) For 93051, 93052, 93053, 93054, 93055 model:

- a) Peel apart the sterile package.
- b) Hold the handle and place the sampling swab on the inner wall of the mouth and the upper surface of the tongue.
- c) Keep it for at least 2 minutes until it is full of saliva, soft and swelling, and then take it out to complete the sample collection.

[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) *² 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) *³ 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) *⁴ 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:

93050E/93050HZ-163/FS740 Maximum breaking strength 28N

93050L/93050M Maximum breaking strength 2~35N.

93050LS/93050MS 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 $\geq 0.02g$.

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

(Note: *1 indicates not applicable to model 93051, 93052, 93053, 93054, 93055.

*2 indicates not applicable to model FS740.

*3 indicates not applicable to model 93050LS, 93050MS, 93051, 93052, 93053, 93054, 93055.

*4 indicates only applicable to model 93050E-76, 93050E-101, 93050E-152, 93050HZ-163, 93050L, 93050M, 93050LS, 93050MS, FS740.)

[Period of Validity]

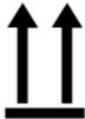
36 months

[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