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| Miraclean Technology Co., Ltd. | CE Technical File | File No | MRC-CE-DMS-003-02.1 | Version | V1.0 |
| | Instruction for Use | Effective Date | 2022-11-28 | Page | 1 / 6 |



Instructions for Use

Of

Disposable Medical Swab

Model: 93050E-152, 93050E-101, 93050E-76, 93050F-150, 93050F-103, 93050F-76, 93050G-150, 93050G-103, 93050G-76, 93050H-163, 93050H-100, 93050H-76, 93050L, 93050M, 96000D, 96000E, 96000F, 96000G, 96000GP, FS740, MCA-T260, MCA-T105, MCA-T003, FS707, FS708

Revision records:

| Edition | Effective Date | Summary of revision | Approved by | Audited by | Written by |
|---------|----------------|---------------------|-------------|------------|------------|
| V1.0 | 2022.11.28 | Initial version | Zhai Ying | Cui Liu | Chen Miao |
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Instructions for Use

[Product Name]

Disposable Medical Swab

[Product Model]

93050E-152, 93050E-101, 93050E-76, 93050F-150, 93050F-103, 93050F-76, 93050G-150, 93050G-103, 93050G-76, 93050H-163, 93050H-100, 93050H-76, 93050L, 93050M, 96000D, 96000E, 96000F, 96000G, 96000GP, FS740, MCA-T260, MCA-T105, MCA-T003, FS707, FS708

[Packaging Specification]

Single package: 1pc/bag

Sales Package: 1) 25pcs/bag; 100pcs/bag (except for MCA-T260, MCA-T105, MCA-T003)

2) 10pcs/bag (only for MCA-T260, MCA-T105)

3) 20pcs/bag (only for MCA-T003)

[Intended Use]

The Disposable Medical Swab is intended to provide in sterile form, application for surface cleaning, wiping, and disinfection.

[Scope and Limitations of Application]

Used by medical and health units and family health care.

[Description]

| Model | Description |
|---|--|
| 93050E-152, 93050E-101, 93050E-76, 93050L, 93050M, 96000D, 96000G, 96000GP, FS740 | The Disposable medical swab consists of a plastic handle, breakpoint and sponge swab tip. The long handle is easy to hold and suitable for different groups of people. |
| 93050F-150, 93050F-103, 93050F-76, 93050G-150, 93050G-103, 93050G-76, 93050H-163, 93050H-100, 93050H-76, 96000E, 96000F, MCA-T260, MCA-T105, MCA-T003, FS707, FS708 | The Disposable medical swab consists of a plastic handle and sponge swab tip. The long handle is easy to hold and suitable for different groups of people. |

[Model Difference List]

| NO. | Model | Tip Width (mm) | Tip Length (mm) | Break Length (mm) | Total Length (mm) |
|-----|------------|-------------------|--------------------|----------------------|----------------------|
| 1. | 93050E-152 | 8.5 | 25 | 35 | 152 |
| 2. | 93050E-101 | 8.5 | 25 | 35 | 101 |
| 3. | 93050E-76 | 8.5 | 25 | 35 | 76 |
| 4. | 93050F-150 | 6.5 | 25 | / | 150 |
| 5. | 93050F-103 | 6.5 | 25 | / | 103 |
| 6. | 93050F-76 | 6.5 | 25 | / | 76 |
| 7. | 93050G-150 | 8.5 | 25 | / | 150 |
| 8. | 93050G-103 | 8.5 | 25 | / | 103 |
| 9. | 93050G-76 | 8.5 | 25 | / | 76 |
| 10. | 93050H-163 | 6 | 17 | / | 163 |
| 11. | 93050H-100 | 6 | 17 | / | 100 |
| 12. | 93050H-76 | 6 | 17 | / | 76 |
| 13. | 93050L | 4 | 15 | 78 | 153 |
| 14. | 93050M | 4 | 15 | 95 | 153 |
| 15. | 96000D | 3 | 14.5 | 77 | 153 |
| 16. | 96000E | 3.6 | 11 | / | 68 |
| 17. | 96000F | 3.5 | 11 | / | 150 |
| 18. | 96000G | 4 | 15 | 45 | 75 |
| 19. | 96000GP | 4 | 15 | 45 | 74 |
| 20. | FS740 | 6 | 17 | 55 | 163 |
| 21. | MCA-T260 | 51.5 | 56.5 | / | 216 |
| 22. | MCA-T105 | 45 | 45 | / | 185 |
| 23. | MCA-T003 | 35 | 35 | / | 120 |
| 24. | FS707 | 17 | 27 | / | 129 |
| 25. | FS708 | 19.5 | 27 | / | 125 |

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) If any damage of package, please do not use it.
- 5) If it is expired, please do not use it.
- 6) If you are allergic to sponge and plastic material, please do not use it.
- 7) 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) Apply the swab for surface cleaning, wiping and disinfection.

[Product Performance Index]

- 1) Basic dimensions: Basic dimensions of the product shall meet the requirements of the Model Difference List Form.
- 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 swab 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 swab 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) Sterility: The product should be sterile after ethylene oxide sterilization.

*(Note: * indicates only applicable to model 93050E-152, 93050E-101, 93050E-76, 93050L, 93050M, 96000D, F5740, 96000G, 96000GP.)*





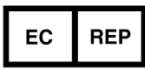


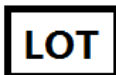




[Period of Validity]





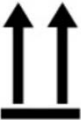
36 months

[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 |

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|---|---|---|---|
| | | | 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. | / | / |



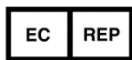
Miraclean Technology Co., Ltd.

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

WEB: <https://www.mantacc.com>

Email: info@mrctek.com



Share Info GmbH

Heerdter Lohweg 83, 40549 Düsseldorf, Germany

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