MP1301AST

CleanWIPE® Small Tip Foam Swab

INSTRUCTIONS FOR USE

The Sterile CleanWIPE® Small Tip Foam Swab is intended to be used for the collection of specimens containing viruses or bacteria from the nasopharynx.

Expected product shelf life: 3 Years

It is recommended that the user or Healthcare Professional using the swab puts on Sterile Personal Protective Equipment, such as gloves, mask and glasses / goggles before performing this procedure.

- The plastic film of the swab pouch is to peeled open at the arrow mark to the half-length mark of the swab.
- Remove the nasopharyngeal swab from its pouch by using index finger and thumb of the same hand.
- The person to be swabbed is to tilt their head back by about 70 degrees.
- The user or Healthcare Professional should hold the nasopharyngeal swab at the notched point of the handle. However, this position can be varied dependent on patient or facial area.
- Gently insert the foam tip end of the nasopharyngeal swab into the nostril of the person.
- The handle of the nasopharyngeal swab should be parallel to the palate during insertion. (Straight horizontally in and NOT upwards)
- Insertion to stop when the foam tip reached the nasopharynx wall, where a resistance would be experienced by the Healthcare Professional at this point. This insertion depth is about the distance between the edges of the nostril to the edge of the ear hole on the same side.
- Gently rotate the foam tip against the nasal wall for about five rotations.
- Slowly withdraw the nasopharyngeal swab from the nostril.

Once the sample is taken, please follow the instructions for use provided by the test kit manufacturer for testing.

In order to use product safely, check before use:

⚠ **Do not use if there is a:**

- Visible split or torn foam tip
- Visible particulates
- Prominent discoloration of swab handle and / or foam tip
- Deformation of swab handle
- Visible melting of foam tip
- Displacement of swab tip
- Broken swab handle
- Open and / or torn pouch

Symbols used on the labels and the Instructions for Use:

Symbols	Description
LOT	**Batch code**: To signify the current LOT number
	**Use by date**: To signify the date by which the product must be used, expressed as YYYY-MM-DD, where YYYY = Year, MM = Month, DD = Day
	**Manufacturer**: Indicates the medical device manufacturer as defined in applicable medical device regulations
	**Manufacture Date**: Indicates the date when the medical device was manufactured
REF	**Catalogue number**: Indicates the medical device manufacturer's catalogue number so that the medical device can be identified
	**Warning symbol**: Do not re-use; For single use only
CE 2797	**C E Mark** To denote that the product meets the requirements of Regulation (EU) 2017/745 and the Notified Body is number 2797, BSI The Netherlands BV
UDI	**Unique Device Identifier (UDI) symbol:** A unique numeric or alphanumeric code related to a medical device.
STERILE R	**Sterilization symbol:** Sterilized by Irradiation
EC REP	**Authorised European Representative:** The body appointed by Foamtec to look after their interests in the European Union
	**See instructions for use:** Indicates the need for the user to consult the instructions for use
	**DO NOT USE IF PACKAGE IS DAMAGED:** Indicate that the device must not be used if the package holding the device is damaged, for example on unpacking of the medical device
MD	**Medical Device:** This denotes that the product is a medical device and meets the requirements of Regulation (EU) 2017/745

	**Radiation indication sticker:** If red, the product is sterilized by irradiation. A yellow colour denotes that the product has not been sterilized
	**Warning symbol:** Read warnings

Symbols	Description
	**Fragile, handle with care**
	**Keep dry**
	**This way up**
	**Keep away from sunlight**
	**Temperature Limit** (Temperature storage range recommended between 2 - 40 °C)

 ***Serious incident***

In the event that any serious incident that has occurred in relation to using the swab, this should be reported to Foamtec International Co., Ltd. If it has occurred in the EU then the EU Representative shall be contacted, whose contact details are shown below, together with the competent authority of the Member State in which the user and / or patient is located.

 **Manufacturer:**

Foamtec International Co., Ltd.
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Representative for US and Singapore products:

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EC REP **EU Representative:**

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