MP1302ST and MP1302ET

CleanWIPE® Medium Tip Foam Swab

# INSTRUCTIONS FOR USE

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

Product shelf life: 3 Years

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

Oro Part

- 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 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 slightly and stick their tongue out. If necessary, use a tongue depressor to push the back of the tongue down and expose the tonsil area.
- Insert the swab, avoiding touching the teeth, tongue and other structures.
- Extend the swab into the pharynx, wipe the swab on the bilateral pharynx tonsils and the posterior pharynx wall for 3-5 times.
- Slowly withdraw the swab carefully, taking care not to touch any other part of the mouth.

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

**In order to use the swab 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**:<br>To signify the current LOT number |
| | **Use by date**:<br>To signify the date by which the product must be used, expressed as YYYY-MM-DD, where YYYY = Year, MM = Month, DD = Day |
| | **Manufacturer**:<br>Indicates the medical device manufacturer as defined in applicable medical device regulations |
| | **Manufacture Date**:<br>Indicates the date when the medical device was manufactured |
| REF | **Catalogue number**:<br>Indicates the medical device manufacturer's catalogue number so that the medical device can be identified |
| | **Warning symbol**:<br>Do not re-use; For single use only |
| CE 2797 | **C E Mark**<br>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:**<br>A unique numeric or alphanumeric code related to a medical device. |
| STERILE R | **Sterilization symbol:**<br>Sterilized by Irradiation |
| STERILE EO | **Sterilization symbol:**<br>Sterilized by Ethylene Oxide |
| EC REP | **Authorised European Representative:**<br>The body appointed by Foamtec to look after their interests in the European Union |
| | **See instructions for use**:<br>Indicates the need for the user to consult the instructions for use |

| | |
|---|---|
|  | **DO NOT USE IF PACKAGE IS DAMAGED**:<br>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**:<br>This denotes that the product is a medical device and meets the requirements of Regulation (EU) 2017/745 |

| Symbols | Description |
|---|---|
|  | **Warning symbol**:<br>Read warnings |
|  | **Radiation indication sticker:**<br>If red, the product is sterilized by irradiation. A yellow colour denotes that the product has not been sterilized |
|  | **Ethylene Oxide indication sticker:**<br>If blue, the product is sterilized using Ethylene Oxide. A red colour denotes that the product has not been sterilized |
|  | **Fragile, handle with care** |
|  | **Keep dry** |
|  | **This way up** |
|  | **Keep away from sunlight** |
|  | **Temperature Limit**<br>(Temperature storage range recommended between 2 - 40 °C) |

REF MP1302ST denotes that the swab has been sterilized using irradiation

REF MP1302SE denotes that the swab has been sterilized using Ethylene Oxide gas

The Instructions for Use can be found on website:

***Serious incident***

In the event that any serious incident 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 overleaf, together with the competent authority of the Member State in which the user and / or patient is located.

**Manufacturer:**

Foamtec International Co., Ltd.
259/1 & 259/2 Moo 3, Laem Chabang Industrial Estate,
Toongsukhla, Sriracha,
Chonburi 20230,
Thailand
Tel:(+66) 33 678 877 Ext. 821 Fax: (+66) 33 678 876
599 7347
e-mail: csth@foamtecintl.com

**Representative for US products:**

Foamtec International LLC,
720 Venture Drive,
Waco,
Texas 76712,
USA
Tel: (+1) 760 599 6342 Fax: (+1) 760

When shown on the label, the product will have been manufactured at Foamtec International, LLC:

Foamtec International, LLC,
6575 IH-35 N
Waco,
Texas 76705,
USA
Tel: (+1) 254 708 8100 Fax: (+1) 254 708 8111
e-mail: customerservice@foamtecusa.com

**EC REP EU Representative:**

**Obelis s.a.**

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Tel: (+32) 27 325 954