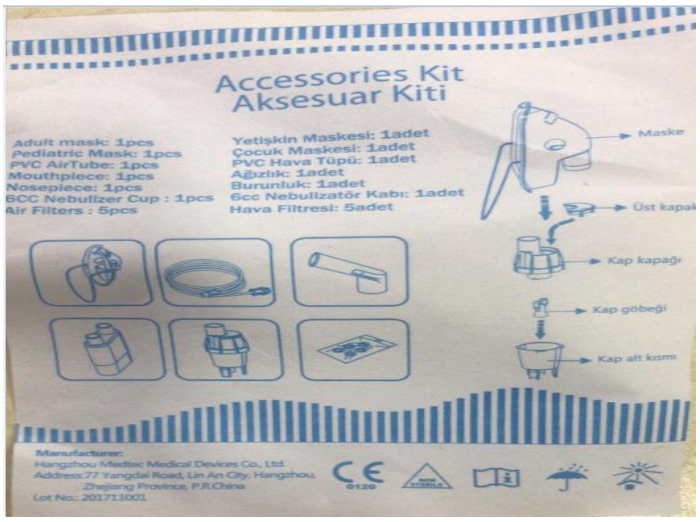
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Nebuliser masks

Priority 1 – For Immediate Action



HPRA Safety Notice: SN2019(06) **Issue Date: 4th February 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Hangzhou Medtec Medical Devices Co., Ltd	MS38606

ISSUE

The HPRA has been informed that nebuliser masks have been placed on the European market without appropriate CE certification. As such, their safety and performance cannot be assured.

The affected nebuliser masks relate to **Lot No. 201711001** only. This number is displayed on the device labelling (See extract image below).

This safety notice is to alert users and healthcare professionals not to use these devices. The HPRA has been unable to determine if the affected lot of devices has been placed on the Irish market and we are issuing this safety notice as a precautionary measure.

ACTION OR RECOMMENDATIONS

The HPRA advises that users and healthcare professionals:

1. Examine your stock to determine if your device displays the affected lot number.
2. Stop using the affected devices immediately and use an alternative nebuliser mask.
3. Identify patients who may have an affected device and replace it with an unaffected device.
4. Forward a copy of this safety notice to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
5. Report the detection of suspected counterfeit devices to the HPRA.

TARGET GROUPS

Hospital Managers / CEOs Risk Managers Pharmacists Paediatricians Community Nurses	Purchasing Managers Stores / Supplies Managers General Practitioners

BACKGROUND

The HPRA has been informed by another EU regulatory authority that CE marking (CE 0120) has been counterfeited for the above referenced lot of nebuliser masks. The manufacturer, Hangzhou Medtec Medical Devices Co Ltd, has confirmed this is not a genuine lot.

This safety notice is to alert users and health care professionals to examine their stock and stop using any affected medical devices identified.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

There are no contact details for this manufacturer.

Telephone: N/A
E-mail: N/A

Enquiries to the **distributor** should be addressed to:

There are no contact details for the distributor.

Telephone: N/A
E-mail: N/A

HPRA CONTACT INFORMATION

All **queries relating suspected counterfeit devices** should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devices@hpra.ie
Website: www.hpra.ie