

# Safety Notice

## Medical Devices

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### Counterfeit NSK Contra Angle Ti-Max Z95L Dental Handpiece

**Priority 2 – Warning**



HPRA Safety Notice: SN2017(32)

Issue Date: 15 September 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
<b>Manufacturer of genuine product:</b> NSK	MS32984
<b>Manufacturer of counterfeit product:</b> Unknown	

#### ISSUE

The HPRA is aware counterfeit NSK contra angle Ti-Max Z95L dental hand pieces have been placed on the Irish market. These devices were purchased online from an online store. This notice is to alert users to examine their stock and quarantine any counterfeit devices identified.

The safety and quality of counterfeit medical devices cannot be guaranteed as they may not be manufactured to the required standards or conform to the requirements of the medical devices legislation. Therefore counterfeit medical devices pose a risk to public health and safety.

The HPRA recommends that dentists, and others in the dental profession, take precautions when purchasing dental devices. For further information please refer to a dedicated medical device brochure relating to '*Buying medical devices online*' and to the recent information notice titled '*Caution when Purchasing Dental Devices Online*' both of which are available for download from [www.hpra.ie](http://www.hpra.ie)

## ACTION OR RECOMMENDATIONS

HPRA advises users of the following:

- 1 If you have purchased the above device online, examine your device using the identification details outlined in the additional information section below.
- 2 If you are unsure whether your device is a counterfeit please contact the manufacturer NSK UK using the contact details below for further information.
- 3 If you know the serial number of your device, the manufacturer NSK UK can verify the authenticity of this device. Please contact the manufacturer for further details.
- 4 Exercise caution when purchasing these or similar medical devices online or from unknown sources.

If you identify or suspect that you have been supplied with product that is counterfeit please quarantine all product and contact the HPRA and NSK UK using the contact information below.

## TARGET GROUPS

Dentists  
Dental Nurses  
Clinical Dental Technicians

Dental Technicians  
Distributors

## MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** (of genuine product) should be addressed to:

**NSK United Kingdom Ltd**

Office 5  
Gateway 1000  
Arlington Business Park  
Whittle Way  
Stevenage  
SG1 2FP  
United Kingdom

**Telephone:** 00 44 1438 310678

**E-mail:** [SNichols@NSK-UK.com](mailto:SNichols@NSK-UK.com)

## HPRA CONTACT INFORMATION

All **counterfeit and non-compliant medical device issues** 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](mailto:devices@hpra.ie)  
**Website:** [www.hpra.ie](http://www.hpra.ie)

## ADDITIONAL INFORMATION

The following images provide a visible comparison of the main differences between the genuine and the counterfeit NSX Ti Max Z95L Contra angle hand piece.

**Please note the identification features listed below are specific to the NSX Ti Max Z95L Contra angle hand piece only and may not be applicable to other NSK contra angle hand piece.**

1. Both the head, head cap and middle joint are larger and ill-fitting compared to the genuine item. The counterfeit device is heavier and appears darker in colour.



- The markings of the genuine device (bottom) are in a different order and include a QR code compared to the counterfeit device (top).



- On the genuine device (left) the **DURA GRIP** logo is placed on the handle shaft, compared to the counterfeit device (right) where a **DURA COAT** logo is placed close to the head.



4. The head size of the counterfeit device is much larger than the genuine instrument and the position of the four water outlets are offset.

