

Safety Notice

Medical Devices

UPDATE

Counterfeit Prime & Bond NT Refill



Priority 3 – Advisory

HPRA Safety Notice: SN2016(12)

Issue Date: 29 April 2016

Revision Date: 12 May 2016

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Manufacturer of genuine product: Dentsply De Trey GmbH	MS27526
Manufacturer of counterfeit products: Unknown	

ISSUE

The HPRA issued a Safety Notice (Ref: SN2016(12)) on 29th April 2016 highlighting that counterfeit Prime & Bond NT Refill bottles have been placed on the European market. The HPRA have since been made aware that the images provided by the manufacturer in the Safety Notice SN2016(12) are not adequate to allow for reliable identification of counterfeit products. Following further clarification by Dentsply De Trey, it is now advised to only use **lot numbers** to identify counterfeit product. The lot numbers may be seen on the outer carton and on the bottle itself. Please see below for further details. Currently, there is no evidence that the counterfeit product has been sold in Ireland. This notice is to alert users to examine their stock for the below mentioned counterfeit lot numbers, quarantine, where necessary and to check future stock for further possible counterfeit items.

ACTION OR RECOMMENDATIONS

HPRA advises users of the following:

- 1 Check current stock and previous purchasing records for the counterfeit lot numbers **1511000479** (expiring 2018-11) **and 1304000648** (expiring 2017-12). If identified, do not use any remaining stock and quarantine immediately as it is not genuine product.
- 2 Where procedures have been completed with a counterfeit lot, there is a risk the filling will de-bond and appropriate corrective action should be taken.
- 3 If you are unclear whether your stock is affected please contact the HPRA and Dentsply De Trey using the contact details below for further information.
- 4 Additional information is available on the manufacturers' website [here](#).

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

TARGET GROUPS

Dentists

Dental Technicians

Dental Nurses

Distributors

MANUFACTURER CONTACT INFORMATION

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

Dentsply De Trey GmbH
De-Trey-Strasse 1, 78467, Konstanz
,Germany

Telephone: +44(0) 1932 853 422 Request the
Regulatory Affairs Department
E-mail: Enquiry.uk@dentsply.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
Website: www.hpra.ie