



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte
Seirbhís Aisíocaíochta Cúraim Phríomhúil
Plás J5
Lárionad Gnó na Páirce Thuaidh
Bealach Amach 5, M50
An Bóthar Thuaidh
Fionnghlas
Baile Átha Cliath 11
D11 PXT0

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Primary Care Reimbursement Service
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Circular 020/16

5th May 2016

Dear Contactor,

Please find the attached safety notice received at Primary Care Reimbursement Service regarding the possible circulation of counterfeit Prime and Bond NT refill bottles.

Since the attached notice was issued, product which match the given batch numbers have been found in Ireland.

Additional suspect product has been found which does not match the batch numbers but has the physical identifiers on the labelling which matches that being circulated in the HPRA safety notice.

Can you please examine the stock currently used within your premises in an effort to ensure they do not correspond to the counterfeit stock as outlined in the attached notice.

If a counterfeit product is identified please contact HPRA on 01-6764971 or email devices@hpra.ie and please advise QPS.PrimaryCare@hse.ie.

I appreciate your co-operation in relation to this matter

Yours sincerely,

Anne Marie Hoey
Assistant National Director
Primary Care Reimbursement Service

Safety Notice

Medical Devices

Counterfeit Prime & Bond NT Refill



Priority 3 – Advisory

HPRA Safety Notice: SN2016(12)

Issue Date: 29 April 2016

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

ISSUE
<p>The HPRA has become aware that counterfeit Prime & Bond NT Refill bottles have been placed on the European market. There is no evidence that the counterfeit products have been sold in Ireland. This notice is to alert users to examine their stock for the above counterfeit lot numbers, quarantine, where necessary and to check future stock for further possible counterfeit items.</p>

ACTION OR RECOMMENDATIONS
<p>HPRA advises users of the following:</p> <ol style="list-style-type: none"> 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 Examine labelling of current and future stock for counterfeit product using the identification details outlined in the additional information below.
- 3 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.
- 4 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.
- 5 Additional information is available the manufacturers website at the following link: <http://www.dentsply.eu/docs/indexv2.aspx?id=31138&domid=1042&sp=E&m1=31072&m2=31130&m3=31138>

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	
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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

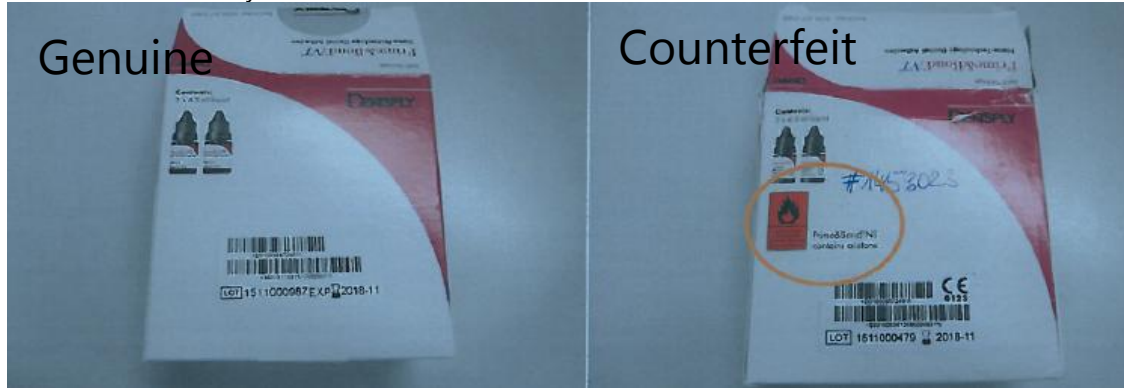
E-mail: devices@hpra.ie

Website: www.hpra.ie

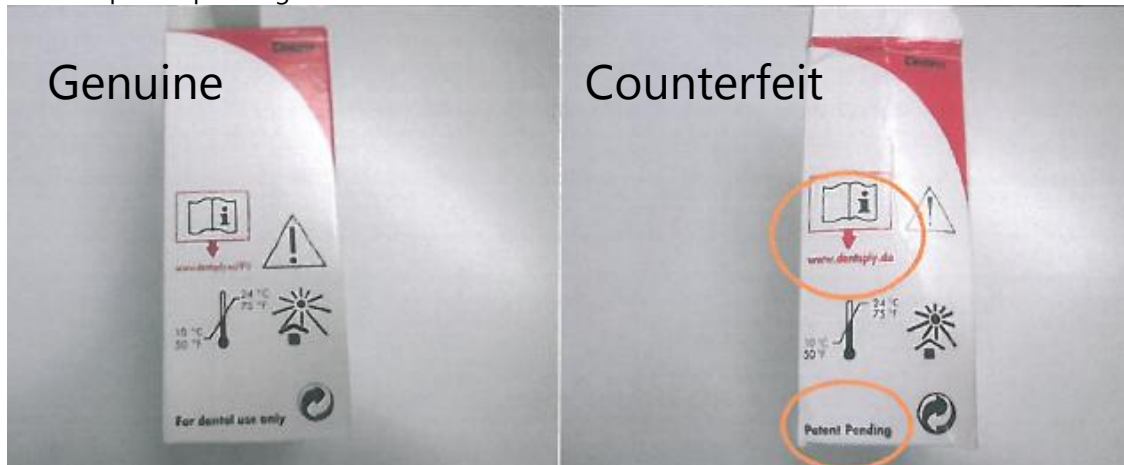
ADDITIONAL INFORMATION

In addition to the confirmed counterfeit lot numbers identified above, the following images provide a visible comparison of the main differences between the genuine and the counterfeit product.

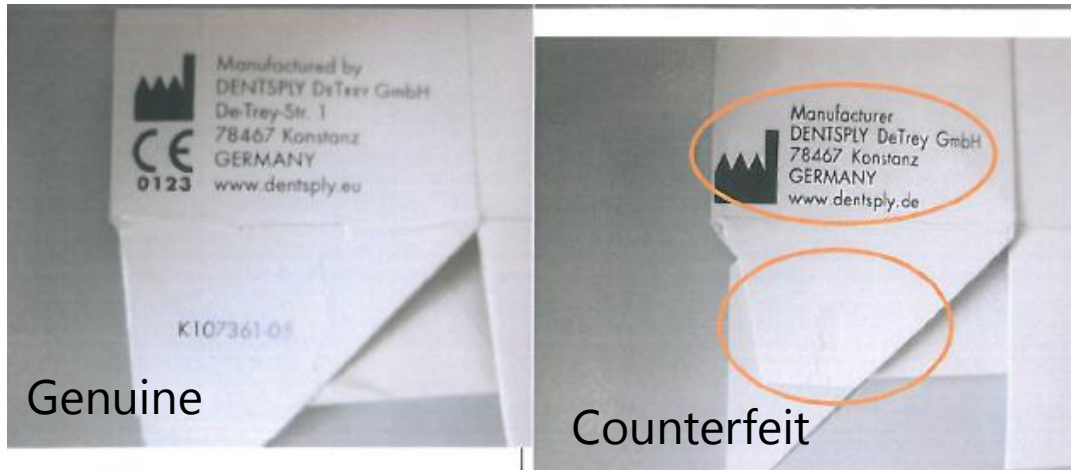
1. The front view of the outer carton of the counterfeit product displays an additional flammable symbol.



2. The side view of the outer carton of the counterfeit product displays an additional 'patent pending' label.



3. The opposite side view of the outer carton of the counterfeit product is missing the CE mark beside the manufacturer's details.



4. The bottle label of counterfeit product displays the CE mark in the incorrect location and an additional flammable symbol.

