



Republic of the Philippines  
Office of the President  
**DANGEROUS DRUGS BOARD**

3/F, DDB – PDEA Building, NIA Road, National Government Center, East Triangle, Diliman, Quezon City, Philippines  
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**BOARD RESOLUTION NO. 78**  
**Series of 2013**

**SUBJECT: GRANTING EXEMPTION FROM SPECIFIC MEASURES OF REGULATORY CONTROL REQUIREMENTS TO CERTAIN FINISHED PRODUCT DENTSPLY (PHILS.) INC.**

**WHEREAS**, under Section 81 (b) and (r) of Article IX of RA 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002, the Board issued Board Regulation No. 3, Series of 2003 which provides for the “Comprehensive Guidelines on Importation, Distribution, Manufacture, Prescription, Dispensing and Sale of, and Other Lawful Acts in Connection with any Dangerous Drugs, Controlled Precursors and Essential Chemicals and other Similar or Analogous Substances”;

**WHEREAS, DENTSPLY (PHILS.) INC.** with business address at 5/F ICARE Bldg. 167 Legaspi Cor. Dela Rosa St. Legaspi Village, Makati City, Philippines is seeking exemption from regulatory measures to the product **SELF CURE ACTIVATOR containing 70% Acetone** (included in Dentsply kit preparation of Calibra Trial Kit and Dentsply Core & Post System);

**WHEREAS**, Section 4(2-d, e & f), Article II of the same Regulation also provides that the Board may exempt from specific measures of regulatory control requirements any preparation with liquid chemical mixture containing less than 30% by weight of the Table II chemical; or solid, semisolid and highly viscous chemical mixture containing Table II chemical; or when the Board is satisfied that the mixture is formulated in such a way that the controlled chemical cannot be easily used for the illicit manufacture of a dangerous drug and that the controlled chemical or chemicals contained in the mixture cannot be readily recovered;

**WHEREAS**, to assist the Board in evaluating requests for exemption, it promulgated Board Resolution No.1 Series of 2008 entitled “**Creating a Technical Working Group (TWG) to assist the Board in considering request of Manufacturers and Importers of finished products from specific measures of regulatory control requirements**”;

**WHEREAS**, it has been determined by the DDB Technical Working Group (TWG) that **DENTSPLY (PHILS.) INC** is a company committed to provide dental community with innovative, high quality, cost effective products. The company is duly registered with PDEA and handler of **P5I-01406001-R030 /P3-0146001-R026 Licenses** as Importer/Distributor and end-user of controlled chemicals. These licenses were issued on **11 June 2012 and valid until 09 June 2013**;

**WHEREAS**, after due deliberation and evaluation, the TWG decided to recommend to the Board the exemption of **DENTSPLY (PHILS.) INC**’ finished products that contain controlled chemicals below and above the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d, e & f);

**WHEREAS**, after satisfying the requirements stipulated under the above mentioned regulations, **DENTSPLY (PHILS.) INC. products is no longer covered by the provisions of Section 10 (Application for import, export or transit permits), Section 11 (Grant of import, export or transit permits), and Section 22 (Licensed operators NOT to deal with unlicensed operators) of BR No.3, S. 2003.**

**WHEREFORE**, be it **RESOLVED**, as it is hereby **RESOLVED**:

- a. **TO GRANT EXEMPTION** and the issuance of Board Resolution of Exemption, which **shall be valid for one (1) year unless revoked**, to **DENTSPLY (PHILS.) INC' products** containing controlled chemicals below the 30% threshold of the Table II chemicals, in accordance with the provisions of Section 4-2(d& f).
- b. **That the above cited exemptions shall still be subject to the following conditions:**
  - (1) That **DENTSPLY (PHILS.) INC.** shall secure a license from the PDEA and comply with the reporting requirements as provided for in Board Regulation No. 3, Series of 2003;
  - (2) The Board shall strictly monitor subject finished products from their importation to distribution to end-users;
  - (3) The DDB-PDEA Monitoring Team shall have free access to **DENTSPLY (PHILS.) INC.** premises where the finished products is kept and/or used;
  - (4) That **DENTSPLY (PHILS.) INC.** shall assume full responsibility for any misuse of the imported finished product, caused either by its own negligence or by negligence of all persons acting under their name or control and supervision; and
  - (5) Any violation of the provisions of Board Regulation No. 3, Series of 2003, shall be a ground for the revocation of the certificate of exemption at anytime and would be dealt with severely.

**APPROVED and ADOPTED** this 6<sup>th</sup> day of May, in the year of Our Lord, 2013 in Pampanga.

(Sgd) **Secretary ANTONIO A. VILLAR, JR.**  
Chairman, Dangerous Drugs Board

Attested:

(Sgd) **Undersecretary JOSE MARLOWE S. PEDREGOSA**  
Secretary of the Board